Post-Market Active Surveillance and Health Economic Evaluation of Cerebrovascular Diagnostic and Therapeutic Devices

(Study Protocol)

Version: 1.0

Version Date: September 10, 2025

Institution: Neurovascular Center, Changhai Hospital, Naval Medical University

Principal Investigator : Yu Zhou, Prof

Study Period: October 2025 to July 2029

Investigator's Declaration and Protocol Signature Page

As the Principal Investigator of this research project, I will adhere to the Measures for Ethical Review of Life Sciences and Medical Research Involving Human Beings (2023), the WMA Declaration of Helsinki (2024), the CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects (2002), and the ethical principles ofthe ethical principles of Good Clinical Practice (GCP). Under the guidance of Good Clinical Practice (GCP), I will conduct this research strictly in accordance with the requirements of the protocol approved by the Ethics Committee. to ensure the scientific integrity of the study and protect the health and rights of study participants.

Name:周宇

Sign: 

Date: September 19, 2025

Study Synopsis

Protocol Title	Post-Market Active Surveillance and Health Economic Evaluation of Cerebrovascular Diagnostic and Therapeutic Devices
Version Number / Version Date	V1.0/2025.09.10
Sponsor	Changhai Hospital, Naval Medical University
Principal Investigator	Yu Zhou
Study Type	Prospective cohort studies
Study Objectives	1.To establish standards for the post-market active surveillance of cerebrovascular disease diagnostic and therapeutic devices and to develop an intelligent surveillance system; 2.To establish a nationwide collaborative network encompassing multi-tiered medical institutions and to conduct a series of cohort studies on cerebrovascular diseases integrated with the surveillance platform; 3.To evaluate the safety, effectiveness, and health economics of cerebrovascular disease diagnostic and therapeutic devices based on the data collected via the network and platform, thereby providing scientific evidence for the full-lifecycle regulation of these devices.
Sample Size	30,000 cases
Study Population	Patients with acute ischemic stroke (AIS), intracranial arterial stenosis (ICAS), extracranial arterial stenosis (ECAS), intracranial aneurysms (IA), or chronic subdural hematoma (CSDH) who undergo cerebrovascular interventional therapy.

Study Methods	To conduct five major prospective cohort studies targeting mechanical thrombectomy for AIS, ICAS, ECAS, IA, and CSDH. The study will collect data throughout the entire clinical pathway (from diagnosis to treatment) to comprehensively evaluate the real-world safety and effectiveness of relevant devices.
Primary Efficacy Endpoints	**Functional outcome:** Modified Rankin Scale (mRS) score at day 90; procedural success rate.
Secondary Efficacy Endpoints	Incidence of procedural complications
Safety Endpoints	Mortality rate at 90 days
Statistical Analysis Methods	Multivariable regression models, propensity score matching, and target trial emulation will be adopted for statistical analyses.
Publication Plan	Peer-reviewed original articles, comprehensive research reports, and expert consensus.

Study Background

Cerebrovascular disease is the leading cause of disability and adult mortality in China, with a high overall incidence. The rapid advancement and widespread application of neurointerventional techniques have driven an annual increase in the volume of cerebrovascular interventional procedures. Consequently, various cerebrovascular diagnostic and therapeutic devices—including multiple domestically developed innovative devices—have gained market approval following pre-market clinical trials, thereby expanding clinical treatment options.

However, pre-market studies are often limited by small sample sizes, restricted population representativeness, short observation periods, and highly controlled clinical environments, making it difficult to fully evaluate device performance in real-world clinical settings. Therefore, strengthening post-market device regulation and establishing a comprehensive post-market active surveillance system are critical. These measures are essential for the timely detection and management of clinical risks, ensuring patient safety, accumulating real-world data (RWD), and supporting the optimization of health policies and healthcare reimbursement decisions.

China has long prioritized the post-market surveillance of medical devices. Since initiating a pilot program for medical device adverse event (MDAE) monitoring in 2002, China successively promulgated the Measures for the Monitoring and Re-evaluation of Medical Device Adverse Events (Trial) in 2008 and the revised Measures for the Monitoring and Re-evaluation of Medical Device Adverse Events in 2018 to strengthen device surveillance. Furthermore, the newly revised *Regulations*

on the Supervision and Administration of Medical Devices (State Council Decree No. 739 of the People's Republic of China), promulgated in 2021, emphasize full-lifecycle, full-process and full-chain oversight of medical devices.

Throughout this progression, China has established the Medical Device Adverse Event Reporting and Management System, anchored by provincial MDAE monitoring centers. This system enables medical institutions and manufacturers that identify adverse events to submit reports, increasing the volume of adverse event submissions and improving risk monitoring and control capacity.

However, it is notable that China's existing post-market regulatory framework for medical devices still faces a significant challenge: the lack of an active surveillance system. The current reporting system, which designates medical device registrants as the primary responsible entities, is voluntary rather than mandatory. This inevitably leads to inherent flaws such as low reporting rates, high misreporting rates, the inability to calculate true incidence rates, and delayed signal detection. Consequently, the real-world safety, effectiveness, and health economics of medical devices cannot be comprehensively evaluated, posing potential risks to public health safety and the efficient utilization of healthcare resources. Therefore, it is imperative to transition from a passive surveillance model to an active surveillance paradigm characterized by proactive data collection and active outcome analysis.

Although active surveillance takes various forms, conducting real-world active surveillance based on healthcare data has become a prevailing trend. This is driven by the enhanced integration and application of healthcare data, alongside continuous

advancements in analytical techniques. For instance, in 2012, the U.S. Food and Drug Administration (FDA) initiated the Medical Device Epidemiology Network (MDEpiNet)—a multi-stakeholder collaborative platform involving healthcare institutions, academic organizations, device manufacturers, and patient advocacy groups. This initiative aims to conduct surveillance research by sharing resources across network members and integrating RWD, including electronic health records (EHR), cohort studies, and healthcare claims data.

In recent years, China has initiated pilot programs for active post-market surveillance of medical devices (i.e., the medical device vigilance system) in regions such as Jiangsu, yielding preliminary results. Overall, however, the implementation of real-world evaluation still faces significant challenges:

1. Lack of a unified national surveillance system: Inefficient cross-hospital collaboration hinders standardized data integration and creates isolated information silos.
2. Absence of a multi-center collaborative network: The surveillance framework is solely regulator-led, leaving healthcare institutions (core data providers) with insufficient incentives for active data submission and early risk alerting.
3. Deficient long-term follow-up workflows: Incomplete longitudinal follow-up data limits the availability of health economic evidence to support healthcare policy design.

China has unique national conditions: a vast territory, large population, heterogeneous

regional epidemiological profiles, and unbalanced socioeconomic and healthcare resources. Combined with the broad clinical adoption of post-market cerebrovascular devices (domestic innovative devices in particular) and the massive volume of real-world data they generate, the above challenges will be further exacerbated when rolling out nationwide active surveillance. Therefore, the successful implementation of active medical device surveillance tailored to China's context relies on several key strategies:

First, coordinating inter-hospital collaboration through departments with core advantages in cross-sector coordination to construct a national system and achieve data harmonization across medical institutions.Second, empowering medical institutions as the primary executing entities of active surveillance by leveraging specialized academic influence to build collaborative networks and research-sharing mechanisms, thereby incentivizing institutional participation.Third, establishing research cohorts with standardized disease follow-up protocols to acquire robust long-term follow-up data for comprehensive longitudinal and health economic evaluations.

Study Objectives

Centered on the theme of "Post-market Active Surveillance and Health Economic Evaluation of Non-pharmacological Interventions and Innovative Devices," this project is jointly carried out with top domestic institutions including the National Center for Medical Administration, regional drug evaluation centers, Beijing Tiantan

Hospital of Capital Medical University, the First Affiliated Hospital of Naval Medical University, the First Affiliated Hospital of Harbin Medical University, and the School of Public Health at Fudan University. The project aims to:

1. Establish active post-market surveillance standards for cerebrovascular diagnostic and therapeutic devices and develop an intelligent surveillance system;
2. Build a nationwide collaborative network covering multi-tier healthcare institutions and conduct a series of cerebrovascular disease cohort studies leveraging the surveillance platform;
3. Evaluate the safety, effectiveness, and health economics of cerebrovascular diagnostic and therapeutic devices based on the data collected through the collaborative network and platform, thereby providing scientific evidence for the full-lifecycle regulation of these devices.

Study Content

Study Population

Patients with acute ischemic stroke (AIS), intracranial arterial stenosis (ICAS), extracranial arterial stenosis (ECAS), intracranial aneurysms (IA), or chronic subdural hematoma (CSDH) who undergo cerebrovascular interventional therapy.

Sample Size Estimation

Based on our preliminary clinical data, this study will recruit all eligible patients diagnosed with the five target cerebrovascular conditions including acute ischemic stroke (AIS), intracranial arterial stenosis (ICAS), extracranial arterial stenosis

(ECAS), intracranial aneurysms (IA), or chronic subdural hematoma (CSDH) ，with a projected total sample size of 30,000 participants.

Specific Study Description

We will establish an active post-market cerebrovascular surveillance network by collaborating with 50 to 60 hospitals across various regions and tiers, deploying the surveillance platform at the network's sentinel sites. Approaching from both ischemic and hemorrhagic disease perspectives, we will conduct prospective registry studies targeting four major diseases: acute large vessel occlusion (ALVO), intracranial arterial stenosis (ICAS), intracranial aneurysms (IA), and chronic subdural hematoma (CSDH).

This initiative delivers full-lifecycle surveillance covering nine categories of devices，encompassing no fewer than 20,000 device cases. These categories include: stent retrievers and aspiration catheters for ALVO; balloons and intracranial stents for ICAS; optical coherence tomography (OCT) systems and vertebral artery ostium drug-eluting stents for extracranial stenosis; flow diverters (FDs) and adjunctive embolization stents for IA; and middle meningeal artery (MMA) embolization materials for CSDH. This setup meticulously fulfills the regulatory guideline requirements that "the surveillance platform must encompass hospitals with regional, disease, and device-utilization representativeness" and "achieve active surveillance for no fewer than 20,000 device cases.

Through the widespread implementation of this platform across the collaborative

network, we will analyze the data for these 9 device categories to accomplish comprehensive active surveillance. During this process, targeted analyses will be dedicated to novel and innovative devices—specifically, the intracranial drug-eluting stent system (Nova Stent), the rapamycin target-eluting stent system for the vertebral artery (Bridge Stent), and OCT—to rigorously evaluate their real-world safety and effectiveness.

Study Methods

1.Eligibility Criteria (Diagnostic Criteria, Inclusion Criteria, and Exclusion Criteria)

(1).Acute Ischemic Stroke (AIS) Cohort

Diagnostic Criteria: Patients with intracranial large vessel occlusion (LVO) confirmed by multi-modal imaging evaluation (CTA/MRA/DSA).

Inclusion Criteria:①Age ≥ 18 years;②Patients with ischemic stroke receiving acute reperfusion therapy (i.e., endovascular thrombectomy, with or without intravenous thrombolysis);③The patient or a legally authorized representative (LAR) has signed the informed consent form (ICF) and is able to comply with the follow-up requirements.

Exclusion Criteria:Has received or is currently participating in other drug or device clinical trials within the past 3 months.

(2).Intracranial Arterial Stenosis (ICAS) Cohort

Diagnostic Criteria: Symptomatic moderate-to-severe intracranial arterial stenosis

(50%-99%, confirmed by DSA) with contralateral intracranial arterial stenosis < 50%, defined as having experienced a transient ischemic attack (TIA), stroke, or other related neurological symptoms caused by internal carotid artery stenosis within the past 6 months.

Inclusion Criteria:①Age 35-80 years;②Symptomatic moderate-to-severe intracranial arterial stenosis (50%-99%, confirmed by DSA) with contralateral intracranial arterial stenosis < 50%, defined as having experienced a TIA, stroke, or other related neurological symptoms caused by internal carotid artery stenosis within the past 6 months;③The patient or an LAR has signed the ICF and is able to comply with the follow-up requirements.

Exclusion Criteria:①Presence of contraindications for stenting;②Has received or is currently participating in other drug or device clinical trials within the past 6 months.

(3).Extracranial Arterial Stenosis (ECAS) Cohort

Diagnostic Criteria:Symptomatic moderate-to-severe stenosis of the proximal internal carotid artery (ICA) or vertebral artery (VA) (50%-99%, confirmed by Ultrasound, CTA, or DSA). Symptomatic stenosis is defined as having experienced a TIA, stroke, or other related neurological symptoms caused by ICA or VA stenosis within the past 6 months; OR Asymptomatic severe stenosis of the proximal ICA or VA (70%-99%).

Inclusion Criteria:①Age 35-80 years;②Meets the diagnostic criteria for either symptomatic (50%-99%) or asymptomatic (70%-99%) stenosis of the proximal ICA or VA;③The patient or an LAR has signed the ICF and is able to comply with the follow-up requirements.

Exclusion Criteria:①Presence of contraindications for interventional treatments such as stenting or balloon angioplasty;②Has received or is currently participating in other drug or device clinical trials within the past 6 months.

(4). Intracranial Aneurysm (IA) Cohort

Diagnostic Criteria: Ruptured or unruptured intracranial aneurysm diagnosed by digital subtraction angiography (DSA); meets the surgical indications for flow diverters (FDs) / intracranial stents / coil embolization.

Inclusion Criteria:①Age ≥ 18 years;②Ruptured or unruptured intracranial aneurysm diagnosed by DSA;③Meets the surgical indications for FDs / intracranial stents / coil embolization;④Has provided informed consent for this project and agrees to undergo follow-up imaging examinations.

Exclusion Criteria:①Concurrent other cerebrovascular diseases;②Concurrent severe systemic diseases with a life expectancy of < 2 years;③History of contrast media allergy;④Refusal or inability to complete follow-up.

(5). Chronic Subdural Hematoma (CSDH) Cohort

Diagnostic Criteria: CSDH confirmed by CT, meeting the indications for middle meningeal artery (MMA) embolization.

Inclusion Criteria:①Age > 18 years;②CSDH confirmed by CT, meeting the indications for MMA embolization;③Has provided informed consent for this project and agrees to undergo follow-up imaging examinations.

Exclusion Criteria:①Presence of indications for craniotomy or emergent subdural hematoma evacuation;②Concurrent severe systemic diseases with a life expectancy

of < 1 year;③History of contrast media allergy, etc.

2.Collection and Management of Surveillance Indicators

Basic Information: Patient demographic information, past medical history, medication history, timing of onset, vital signs upon admission, National Institutes of Health Stroke Scale (NIHSS) score, imaging modalities, and other relevant information.

Process Indicators: Primarily encompasses information related to the patient's interventional treatment process. This includes pre-treatment indication evaluation, surgical modality, pre-operative medication types, intra-operative medication usage, and the surgical procedure (including operational workflows, residual stenosis, etc.). It also covers device information (stent product name, model/specification, registrant, registration certificate number, product batch/serial number, Unique Device Identification [UDI], etc.) and post-operative care, alongside the collection of post-operative vital signs, imaging data, laboratory results, and other auxiliary examination data.

Outcome Indicators: Occurrence of complications, neurological functional status at discharge (modified Rankin Scale [mRS] score), as well as the incidence of stroke and cardiovascular events, patient survival status, mRS, and Barthel Index during short-term (30 days to 3 months) and long-term (1 year and beyond) follow-ups.

Cost Information: Includes surgical fees, device costs, length of hospital stay (LOS), total hospitalization expenses, costs of lost productivity (productivity loss costs), as well as post-discharge rehabilitation and medication costs.

Management of Surveillance Indicators: The electronic data capture (EDC) system

will synchronize all collected data to the tiered active surveillance platform for cerebrovascular non-pharmacological devices developed under Objective 1, ensuring data accuracy and completeness.

3.Outcome Evaluation

(1). Outcome Evaluation for the Acute Ischemic Stroke (AIS) Cohort

Primary Efficacy Endpoints:

Functional outcome: Modified Rankin Scale (mRS) score at 90 days.

Successful recanalization rate: Target vessel reperfusion graded by the expanded Thrombolysis in Cerebral Infarction (eTICI) scale post-thrombectomy.

Secondary Efficacy Endpoints:

Other dichotomous analyses of mRS score: at 90 days post-procedure (0-1 vs. 2-6, 0-3 vs. 4-6, 0-4 vs. 5-6, and 0-5 vs. 6).

Change in stroke severity: assessed by the National Institutes of Health Stroke Scale (NIHSS) score at 24 hours post-procedure.

Change in stroke severity: assessed by the NIHSS score at 7 days post-procedure or at discharge (whichever occurs first).

Proportion of rescue therapy: defined as switching to an alternative mechanical thrombectomy modality (stent retriever or aspiration) if the primary method fails to achieve a target vessel reperfusion of eTICI 2b or 3 after 3 passes.

Final angiographic reperfusion outcomes: proportion of patients achieving ≥ eTICI 2b, ≥ eTICI 2c, and eTICI 3.

Angiographic reperfusion outcomes after the first pass: proportion of patients

achieving ≥ eTICI 2b, ≥ eTICI 2c, and eTICI 3 (First Pass Effect).

Time from groin puncture to successful reperfusion: (≥ eTICI 2c).

Total number of mechanical thrombectomy passes (final).

Embolization into new territory (ENT).

Distal embolization.

Device handling performance: Overall evaluation of device performance (e.g., trackability, retractability) by the operating physician, graded on a 4-point scale (Excellent, Good, Acceptable, Poor).

Safety Endpoints:

Mortality (All-cause).

Intracranial hemorrhage (ICH): including symptomatic intracranial hemorrhage (sICH) and asymptomatic intracranial hemorrhage (aICH).

Other severe adverse events (SAEs): including massive or malignant middle cerebral artery (MCA) infarction, pneumonia (aspiration or other), and contrast media allergy at 7 days post-procedure or at discharge (whichever occurs first).

Procedural complications: including any procedure-related complications, vascular dissection, femoral artery puncture complications, etc.

(2)Outcome Evaluation for the Intracranial Arterial Stenosis (ICAS) Cohort

Primary Efficacy Endpoints:

Any stroke or all-cause mortality within 30 days post-enrollment, and any ischemic stroke in the qualifying artery or revascularization of the qualifying artery from 31 days to 1 year post-enrollment.

Secondary Efficacy Endpoints:

Any stroke in the qualifying artery or all-cause mortality within 90 days post-enrollment;

Any stroke outside the qualifying artery territory (non-qualifying artery stroke) within 90 days post-enrollment;

Modified Rankin Scale (mRS) score at 90 days;

Any stroke in the qualifying artery or all-cause mortality within 1 year post-enrollment;

Revascularization of the qualifying artery within 1 year post-enrollment;

Any stroke outside the qualifying artery territory within 1 year post-enrollment;

mRS score at 1 year;

Composite cardiovascular events within 1 year post-enrollment: including stroke, myocardial infarction (MI), and vascular death;

Quality of life (QoL) assessment at 1 year using the EQ-5D questionnaire;

Residual stenosis rate;

Embolization into new territory (ENT);

Distal embolization;

Device handling performance: Overall evaluation of device performance (e.g., trackability, retractability) by the operating physician, graded on a 4-point scale (Excellent, Good, Acceptable, Poor).

Safety Endpoints:

Mortality (All-cause);

Intracranial hemorrhage (ICH): including symptomatic intracranial hemorrhage (sICH) and asymptomatic intracranial hemorrhage (aICH);

Other severe adverse events (SAEs): including massive or malignant middle cerebral artery (MCA) infarction, pneumonia (aspiration or other), and contrast media allergy at 7 days post-procedure or at discharge (whichever occurs first);

Procedural complications: including any procedure-related complications, vascular dissection, femoral artery puncture complications, etc.

(3)Outcome Evaluation for the Extracranial Arterial Stenosis (ECAS) Cohort

Primary Efficacy Endpoints:

Any stroke or all-cause mortality within 30 days post-enrollment;

Ischemic stroke in the target vessel territory within 1 year post-enrollment;

Revascularization of the target vessel within 1 year post-enrollment.

Secondary Efficacy Endpoints:

Incidence of any stroke or transient ischemic attack (TIA) in the target vessel territory within 3 months post-enrollment;

Incidence of revascularization in the target vessel territory within 3 months post-enrollment;

Incidence of cerebrovascular event-related mortality within 3 months post-enrollment;

Incidence of any cardiovascular or cerebrovascular events within 3 months and 1 year post-enrollment;

Incidence of all-cause mortality within 3 months and 1 year post-enrollment;

Incidence of cardiovascular or cerebrovascular event-related mortality within 3

months and 1 year post-enrollment;

Proportion of patients with an mRS score ≤ 1 or ≤ 2 at 3 months and 1 year post-enrollment.

Safety Endpoints:

Incidence of procedure-related complications (including vascular perforation, vascular dissection, distal embolization, and vasospasm);

Incidence of symptomatic intracranial hemorrhage (sICH) within 7 days post-enrollment;

Incidence of any stroke within 3 months post-enrollment.

(4)Outcome Evaluation for the Intracranial Aneurysm (IA) Cohort

Primary Endpoint:

Complete aneurysm occlusion rate at 12-month follow-up

Secondary Endpoints:

Procedural technical success rate;

Successful occlusion rate of the target aneurysm (defined as Raymond-Roy Class I & II) at 12 months post-procedure;

Incidence of significant stenosis (> 50% stenosis) of the parent artery at 12 months post-procedure;

Incidence of target aneurysm-related disabling stroke or neurological death during the follow-up period;

All-cause mortality rate during the follow-up period;

Retreatment rate of the target aneurysm during the follow-up period;

Device-related complication rate.

(5)Outcome Evaluation for the Chronic Subdural Hematoma (CSDH) Cohort

Primary Endpoint:

Symptomatic recurrence or progression of the subdural hematoma within 90 days post-treatment. (Note: Symptoms are defined as involving one or more of the following neurological symptoms and signs: headache, cognitive impairment, dysarthria or aphasia, ataxia or instability, paresis, sensory loss, and seizures. Recurrence of the subdural hematoma is defined as a maximum hematoma thickness exceeding 10 mm or the requirement for reoperation during follow-up after previous burr-hole drainage. Progression of the subdural hematoma is defined as an increase in maximum hematoma thickness of > 3 mm compared to baseline or the need for surgical rescue among patients receiving conventional treatment.)

Data Safety and Monitoring Plan (DSMP)

1.Overview of Data Management Methods

The project team plans to establish comprehensive platform security specifications, ensuring that all data undergoes strict de-identification processing within the participating hospitals. We will implement data encryption and role-based access control (RBAC) to ensure the platform fully complies with both domestic and international data privacy regulations. Furthermore, we will formulate standardized policies and procedures regarding data usage and sharing. A compliance self-evaluation function will be developed to ensure that the platform operates in

accordance with national policies, laws, and regulations. Additionally, third-party organizations will be commissioned to conduct regular security audits to guarantee data credibility and integrity.

2. Communication with the Ethics Committee and Regulatory Authorities

Internal calendar reminders will be established to ensure that study progress reports are submitted strictly according to the frequency mandated by the Institutional Review Board/Ethics Committee (IRB/EC). During the course of the study, if significant issues arise that may compromise the scientific integrity or ethical standards of the research (e.g., the detection of unexpected major safety signals or systemic difficulties in data collection), the project team will proactively initiate communication with the medical products regulatory authorities.

3. Internal Data Analysis Plan

This Internal Data Analysis Plan is formulated to systematically sort out, process, and analyze all internal data. By digging into the inherent laws, existing problems and potential value of internal data, it provides objective, accurate and data-driven support for operation optimization, decision-making and process improvement. This plan applies to all internal data statistical analysis work of the daily operation, project implementation and other scenarios, and standardizes the whole process of data collection, sorting, analysis, verification and result output to ensure the scientificity, authenticity and effectiveness of internal data analysis results

4. Frequency of Submitting Data Safety and Monitoring Reports to the Ethics Committee

Data Safety and Monitoring Reports will be submitted strictly in adherence to the frequency mandated by the Ethics Committee.

5. Compliance with Ethical Principles and Relevant Regulations

This study will be conducted in strict compliance with the Declaration of Helsinki, Good Clinical Practice (GCP) guidelines, and all applicable national laws and regulations governing medical research and data privacy.

Statistical Analysis Plan (SAP)

After rigorous data cleaning by biostatisticians, real-world clinical data will be analyzed via multivariable regression, propensity score matching and target trial emulation to evaluate the safety and performance of interventional devices. A comprehensive statistical analysis report will be generated, which includes:

Device Evaluation: Assessment of the overall safety and effectiveness of the interventional devices in clinical application, as well as comparisons among different device brands (including the evaluation of overall safety, effectiveness, and head-to-head comparisons of different brands of stent retrievers).

Clinical Strategy Evaluation: A multifactorial analysis of covariates influencing interventional device treatment outcomes—incorporating patient characteristics, lesion characteristics, and procedural variables—to facilitate the development of individualized treatment strategies.

Publication Modalities of Research Outcomes

1. Peer-reviewed original articles: Formal scientific reports based on the findings of this project, initially published in relevant professional academic journals.

2. Expert Consensus: Consistent opinions, recommendations, or clinical positions reached by experts with specialized knowledge and experience in the neurovascular field. These are formulated following systematic discussions and evaluations based on existing scientific evidence and the data from this project, ultimately published in relevant professional journals.

3. Comprehensive Research Reports: Detailed technical and analytical documents submitted to superior competent authorities (e.g., the National Health Commission, the National Medical Products Administration), with a 3-year publication moratorium.