Center for Clinical AI Impact Evaluation

臺中榮民總醫院　公告訊息　AI影響性研究中心

■ **Introduction**

The Ministry of Health and Welfare officially launched its three major AI centers today, with Taichung Veterans General Hospital actively participating as a core member of the **Center for Clinical AI Impact Evaluation**. The third category, the "Center for Clinical AI Impact Evaluation," is a collaboration between the Information Office of the Ministry of Health and Welfare and the National Health Insurance Administration. Its goal is to address challenges in securing National Health Insurance (NHI) coverage for AI medical applications. Since AI product pricing cannot follow the conventional cost assessment model for traditional medical devices, the center will establish a **cross-system, multi-level clinical trial mechanism**. A multidisciplinary team will design research studies to evaluate the clinical effectiveness of AI applications, ensuring they deliver both medical benefits and cost-effectiveness. Additionally, the center will create a **scientific pricing framework** to support policy decisions.

Center for Clinical AI Impact Evaluation, under the Ministry of Health and Welfare's Information Office, will work with the National Health Insurance Administration to address challenges in integrating AI medical applications into the National Health Insurance system. Through research design, the center aims to clarify the scientific relationship between the pricing of smart medical devices and their medical value. The research will establish a **cross-system, multi-level clinical trial mechanism**, formulate common ethical review standards, and conduct AI clinical benefit evaluations through multidisciplinary studies. This ensures AI products meet both **clinical effectiveness and public health benefits** while providing a foundation for scientific pricing.
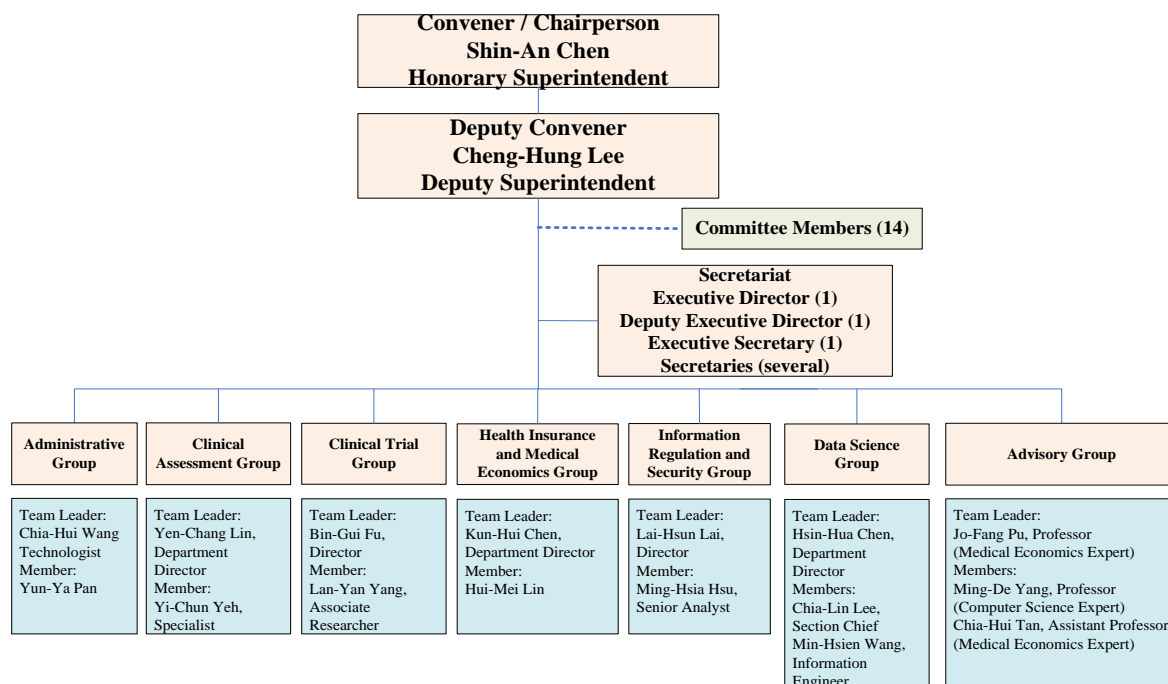(Source: Ministry of Health and Welfare)

Taichung Veterans General Hospital was commissioned by the Ministry of Health and Welfare and officially established the **Center for Clinical AI Impact Evaluation** on September 28, 2024.

Center for Clinical AI Impact Evaluation Team Composition:

- o **Led by** Honorary Superintendent **Shih-An Chen** as the project principal investigator.
- o **Core team members from Taichung Veterans General Hospital:**
  - ▪ **Kun-Hui Chen**, Executive Director of the Smart Medical Committee / Chief AI Medical Information Officer
  - ▪ **Lai Lai-Hsun**, Director of the Information Office
  - ▪ **Pin-Kuei Fu**, Director of the Clinical Trial Center
  - ▪ **Lan-Yen Yang**, Associate Researcher
  - ▪ **Hsin-Hua Chen**, Director of the Department of Digital Medicine
  - ▪ **Yun-Yu Chen**, Associate Researcher at the Department of Medical Research (Epidemiologist / Biostatistician)
  - ▪ **Chia-Lin Lee**, Section Chief of the Department of Digital Medicine (Data Scientist)
- o **External Experts:**
  - ▪ **Ming-De Yang**, Distinguished Professor and Dean of the College of Engineering, National Chung Hsing University (Data Scientist / Computer Scientist)
  - ▪ **Jo-Fang Pu**, Executive Director of the Medical Data Science Center, Fu Jen Catholic University (Healthcare Economics Expert)
  - ▪ **Chia-Hui Tan**, Assistant Professor, Department of Healthcare Management, China Medical University (Healthcare Economics Expert)
- o **Collaborating Hospitals:**
  - ▪ **Kaohsiung Medical University Chung-Ho Memorial Hospital**
  - ▪ **Show Chwan Memorial Hospital, Show Chwan Medical Care   Corporation**

Taichung Veterans General Hospital   Center for Clinical AI Impact Evaluation

■ Organizational Structure

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│     Convener / Chairperson      │
│         Shin-An Chen            │
│    Honorary Superintendent      │
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│        Deputy Convener          │
│        Cheng-Hung Lee           │
│     Deputy Superintendent       │
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                                              │ Committee Members (14)│
                                              └──────────────────────┘
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              │            Secretariat                │
              │     Executive Director (1)            │
              │  Deputy Executive Director (1)        │
              │    Executive Secretary (1)            │
              │      Secretaries (several)            │
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Administrative Group	Clinical Assessment Group	Clinical Trial Group	Health Insurance and Medical Economics Group	Information Regulation and Security Group	Data Science Group	Advisory Group
Team Leader: Chia-Hui Wang Technologist Member: Yun-Ya Pan	Team Leader: Yen-Chang Lin, Department Director Member: Yi-Chun Yeh, Specialist	Team Leader: Bin-Gui Fu, Director Member: Lan-Yan Yang, Associate Researcher	Team Leader: Kun-Hui Chen, Department Director Member: Hui-Mei Lin	Team Leader: Lai-Hsun Lai, Director Member: Ming-Hsia Hsu, Senior Analyst	Team Leader: Hsin-Hua Chen, Department Director Members: Chia-Lin Lee, Section Chief Min-Hsien Wang, Information Engineer	Team Leader: Jo-Fang Pu, Professor (Medical Economics Expert) Members: Ming-De Yang, Professor (Computer Science Expert) Chia-Hui Tan, Assistant Professor (Medical Economics Expert)

■ Cross-Hospital Management Committee Member List

Institution	Representative Category	Name	Position
Taichung Veterans General Hospital	Clinical Representative	Cheng-Hung Lee	Deputy Superintendent
Taichung Veterans General Hospital	Clinical Representative	Kun-Hui Chen	Executive Director, Smart Healthcare Committee
Taichung Veterans General Hospital	Clinical Representative	Hsin-Hua Chen	Director, Department of Digital Medicine
Taichung Veterans General Hospital	Clinical Representative	Tsui-Ling Lin	Director, Department of Internal Medicine
Taichung Veterans General Hospital	Clinical Representative	Sheng-Yang Huang	Deputy Executive Director, Smart Healthcare Committee
Taichung Veterans General Hospital	Clinical Trial Representative	Hsi-Kuei Fu	Director, Clinical Trials Division
Taichung Veterans General Hospital	IT Representative	Lai-Kun Liao	Director, IT Office
Taichung Veterans General Hospital	IT Representative	Ming-Hsia Hsu	Senior Analyst, IT Office
Kaohsiung Veterans General Hospital	Clinical Representative	Chao-Yuan Wang	Superintendent
Kaohsiung Veterans General Hospital	Clinical Trial Representative	Wen-Chih Liu	Attending Physician, Department of Orthopedics
Kaohsiung Veterans General Hospital	IT Representative	Hsin-Chuan Li	Deputy Director, IT Office
Changhua Christian Hospital	Clinical Representative	Shih-Yi Chu	Vice Superintendent, Research & Education
Changhua Christian Hospital	Clinical Trial Representative	Ming-Hsien Hu	Director, Department of Orthopedics
Changhua Christian Hospital	IT Representative	Yu-Wen Yang	Deputy Director, IT Office

■   **Alliance Hospital Organizational Structure**

■   **Members**

Category	Name	Current Position	Field Expertise
PI	Shih-An Chen	Honorary Superintendent, Taichung Veterans General Hospital	Project Lead and Operational Supervision
Co-PI	Chao-Yuan Wang	Superintendent, Kaohsiung Medical University Chung-Ho Memorial Hospital	Collaborating Hospital Coordinator and Project Facilitator
	Pei-Yi Chu	Vice Superintendent of Education and Research, Changhua Show Chwan Memorial Hospital	Collaborating Hospital Coordinator and Project Facilitator
	Ming-De Yang	Distinguished Professor and Dean of the College of Engineering, National Chung Hsing University	Computer Science Expert
	Jo-Fang Pu	Executive Director, Data Science Center, School of Medicine, Fu Jen Catholic University	Health Economics Expert
	Chia-Hui Tan	Assistant Professor, Department of Healthcare Management, China Medical University	Health Economics Expert

Field Experts	Name	Current Position	Specific Roles, Tasks, and Scope in This Project
Chief of AI Medical Informatics (Medical Background)	Kun-Hui Chen	Director, Department of Orthopedics & Executive Director, Smart Healthcare Committee, Taichung Veterans General Hospital	Assists project leaders in coordinating with collaborating hospitals and advancing various project initiatives
Cardiology Specialist	Wei-Wen Lin	Director, Cardiovascular Center & Deputy Executive Director, Smart Healthcare Committee, Taichung Veterans General Hospital	Assists project leaders in coordinating with collaborating hospitals and advancing various project initiatives
Director of Medical Informatics	Lai-Hsun Lai	Director, Information Department & Executive Director, Smart Healthcare Committee, Taichung Veterans General Hospital	Ensures information security and privacy protection, provides IT support, standardizes electronic application forms, and integrates data systems
Epidemiology Expert	Hsin-Hua Chen	Director, Department of Digital Medicine & Deputy Executive Director, Smart Healthcare Committee, Taichung Veterans General Hospital	Integrates and connects data databases, de-identifies clinical trial data, and establishes data-sharing mechanisms
Director of Clinical Trials Center	Pin-Kuei Fu	Director, Clinical Trials Division, Medical Research Department, Taichung Veterans General Hospital	Establishes a Central Institutional Review Board (CIRB) for unified ethics reviews, trains clinical research nurses, and collaborates with IT engineers for clinical trials
Data Science Expert	Chia-Lin Li	Physician, Medical Research Department, Taichung Veterans General Hospital	Integrates and connects data databases, de-identifies clinical trial data, and establishes data-sharing mechanisms

Field Experts	Name	Current Position	Specific Roles, Tasks, and Scope in This Project
Biostatistics Expert	Yun-Yu Chen	Associate Researcher, Medical Research Department, Taichung Veterans General Hospital	Biostatistics Expert
Senior Data Analyst	Ming-Hsia Hsu	Senior Analyst, Information Department, Taichung Veterans General Hospital	Senior Data Analyst
AI Information Engineer	Min-Hsien Wang	Information Engineer, Information Department, Taichung Veterans General Hospital	AI Information Engineer
Clinical Trial Expert	Lan-Yen Yang	Associate Researcher, Medical Research Department, Taichung Veterans General Hospital	Clinical Trial Expert

■ **Center for Clinical AI Impact Evaluation Office**

■ **Contact Information**

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  - **Phone:** +886-4-23592525 ext. 3973
  - **Email:** tcvghaicenter@vghtc.gov.tw
  - **Address:** Research Building, 1st Floor, Room R104, No. 1650, Section 4, Taiwan Boulevard, Xitun District, Taichung City, Taiwan

■ **Flowchart of the Standardized Clinical AI Impact Evaluation Commissioned Research Process**
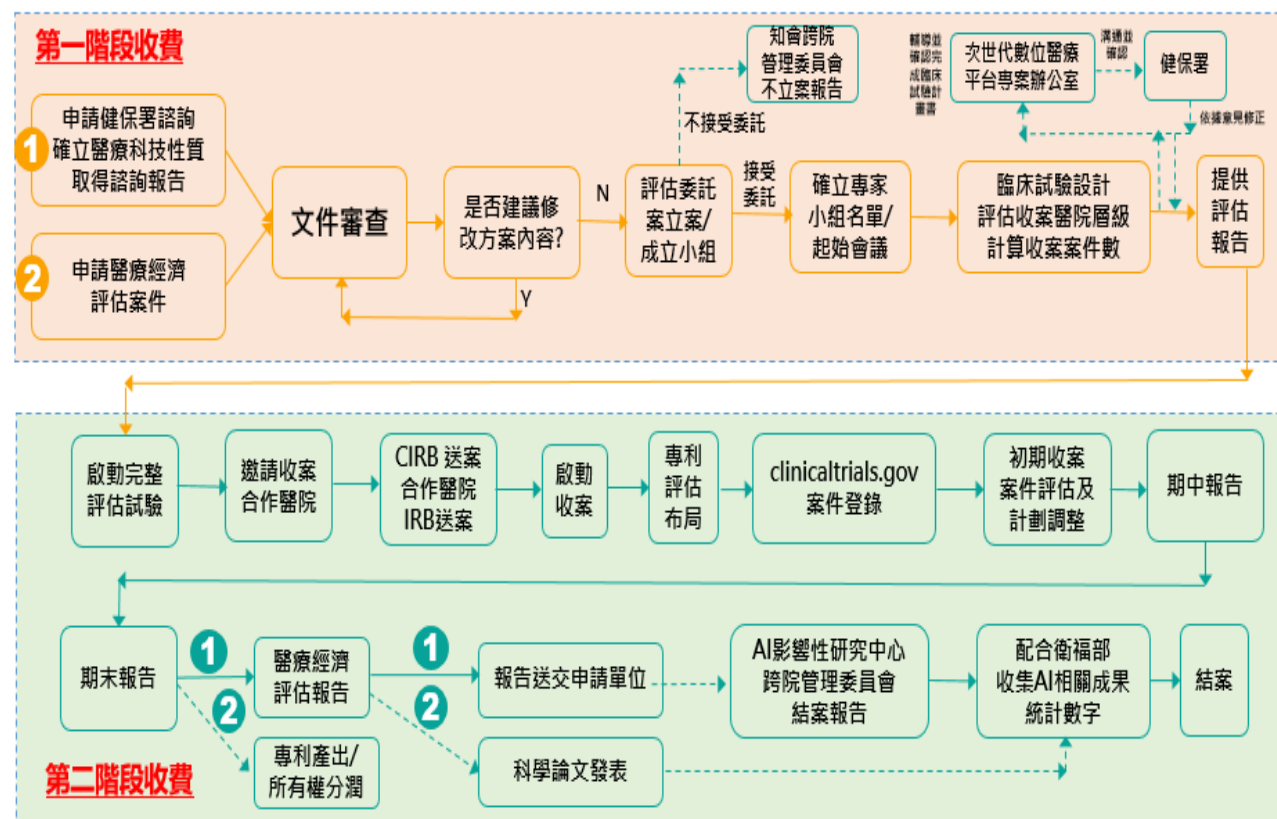
■ **Fee Description**

Item	Operation Model	Fee Structure and Standard Explanation
Medical Economic Evaluation Consultation Fee	1. **Basic Consultation I (for Initial Exploration):** Based on the needs of manufacturers, provide a preliminary economic evaluation execution proposal (1-2 pages), including PICO, recommended application databases, evaluation models, execution timeline, and budget estimation. 2. **Basic Consultation II (for Initial Exploration):** Adjust the content of Basic Consultation I according to manufacturer requirements and provide an execution proposal (1-2 pages), along with one discussion meeting. 3. **Economic Evaluation Study Execution:** After manufacturers submit an economic evaluation application and confirm the budget, the economic evaluation study is carried out. This includes clinical expert consultation, database application, model establishment, and completion of an economic evaluation report (in Chinese or English), with a bilingual summary and submission of a regulatory checklist for the Center for Drug Evaluation.	1. **Basic Consultation I:** NT$5,000 per hour 2. **Basic Consultation II:** NT$5,000 per hour 3. **Economic Evaluation Study Execution:** NT$600,000 - NT$2,000,000 per case
Clinical Trial Expert	The fee package includes:	1. **Trial Protocol Consultation:**

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Taichung Veterans General Hospital   Center for Clinical AI Impact Evaluation

Item	Operation Model	Fee Structure and Standard Explanation
Consultation/Review /Guidance Fee	1. Consultation and guidance on trial design and protocol writing. 2. Budgeting and contract negotiation. 3. Clinical trial statistical support.	NT$47,000 and above 2. **Budgeting and Contract Negotiation:** NT$50,000 and above 3. **Statistical Support for Clinical Trials:** NT$200,000 and above for medical device trials
Data Analysis and Processing Expert Consultation/Guidance Fee	1. Provide consultation and guidance on data analysis and processing related to pre-trial, early case collection, and final study results. 2.Execution of data analysis and processing for early case collection and final study results: Initial data analysis is provided for project evaluation and planning adjustments , while final analysis aligns with Ministry of Health and Welfare statistical reporting requirements.	1. **Consultation and Guidance:** NT$5,000 - NT$10,000 per hour 2. **Execution of Data Analysis and Processing for Early and Final Case Collection:** NT$600,000 - NT$2,000,000 per case
Information System Development and Consultation Fee	Provide IT consulting services and integration planning, as well as FHIR data processing services, to help AI products comply with international interoperability and security standards.	1. **FHIR Data Processing Service Fee:** Charged based on "Basic Fee + Data Processing Fee" (1) **Basic Fee:** NT$100,000 per case. (2) **Data Processing Fee:** Based on "number of case characteristics × number of data entries," with a minimum charge of NT$10,000. If the calculated amount exceeds NT$10,000, it will be charged accordingly.
Administrative Fees	1. **Application Fee:** Basic fee for applying for AI impact evaluation services. 2. **Document Review Fee:** Covers document preparation, completeness review, and evaluation of medical AI impact assessment-related files. 3. **Filing Review Fee:** Covers administrative work, including expert meetings for project evaluation and liaison with the National Health Insurance Administration and next-generation digital healthcare platform office. 4. **Meeting Fee:** Includes venue rental, equipment usage, and administrative support. 5. **Final Report Fee:** Covers the preparation of first-phase and second-phase medical AI impact evaluation reports.	1. **Application Fee:** NT$3,000 per case. 2. **Document Review Fee:** NT$3,000 per case. 3. **Filing Review Fee:** NT$3,000 per case. 4. **Meeting Fee:** NT$3,000 per hour (includes venue rental, equipment usage, and administrative support). 5. **Final Report Fee:** NT$3,000 per phase for administrative processing.