

Overview of the ATLAS project: to establish an international platform for academic clinical trials in Asia



寺田 参省 Mitsumi Terada

国立がん研究センター中央病院
臨床研究支援部門 研究企画推進部 国際研究支援室 医員
Medical Staff, International Trial Management Section,
Research Management Division, Clinical Research Support Office,
National Cancer Center Hospital, Japan

学歴・職歴

- 2009年3月: 東京慈恵会医科大学 卒業
- 2009年4月-2011年3月: 東京慈恵会医科大学附属 柏病院 初期研修医
- 2011年4月-2014年3月: 倉敷中央病院 外科 後期研修医
- 2014年4月-2016年9月: 国立がん研究センター東病院 胃外科 正規レジデント
- 2016年10月-2017年5月: JCOG 臨床研究レジデント
- 2017年6月-2019年5月: EORTC HQ medical research fellow
- 2019年6月-現在: 国立がん研究センター中央病院 臨床研究支援部門 研究企画推進部 国際研究支援室 医員

資格

- 2009年4月 医師免許取得 (医籍番号: 477721)
- 2015年1月 日本外科学会 外科専門医 (No.1005258)
- 2017年4月 日本がん治療認定医機構 がん治療認定医 (No.16100772)
- 2019年3月 医学博士 順天堂大学大学院医学研究科 (甲第2122号)

Academic and Employment Record

- Mar 2009: Graduated from The Jikei University school of Medicine, Japan.
- Apr 2009-Mar 2011: Junior resident, The Jikei University Kashiwa Hospital, Chiba, Japan.
- Apr 2011-Mar 2014: Senior resident (general surgery), Kurashiki Central Hospital, Okayama, Japan.
- Apr 2014-Sep 2016: Resident (Gastric surgery), National Cancer Center Hospital East, Chiba, Japan.
- Oct 2016-May 2017: Clinical Research Resident, Japan Clinical Oncology Group (JCOG)
- Jun 2017-May 2019: Medical Research Fellow (Medical Department), EORTC HQ
- Jun 2019-: Medical staff, International Trial Management Section, Research Management Division, Clinical Research Support Office, National Cancer Center Hospital

License and Certification

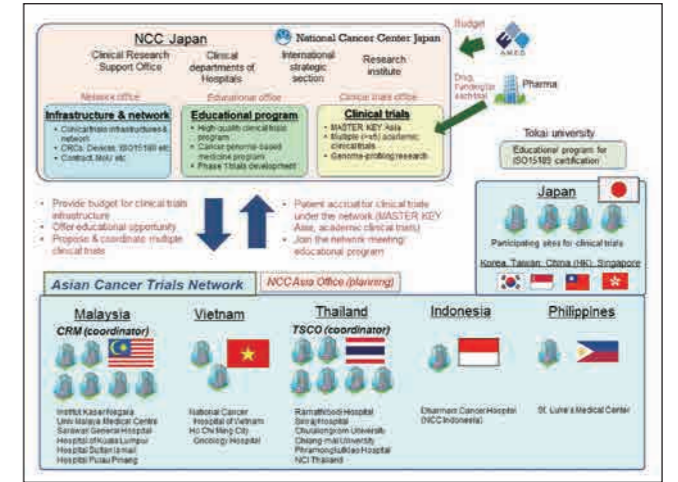
- Apr 2009: Medical license (No.477721)
- Jan 2015: Board Certified Surgeon, General Surgery, Japan Surgical Society (No.1005258)
- Apr 2017: General Clinical Oncologist, Japanese Board of Cancer Therapy (No.16100772)
- Mar 2019: PhD in medicine, Juntendo University Graduate School of Medicine, Japan (Doctoral Degree No. K2122)

国立がん研究センター中央病院は2020年9月よりアジア地域における臨床研究実施体制整備を目的とした「アジアがん臨床試験ネットワーク構築に関する事業: ATLAS project」をAMEDの支援のもとに開始した。ATLAS projectの目的は薬事承認を目指した国際共同試験の恒常的なプラットフォームとしてアジアがん臨床試験ネットワークを日本主導で構築し、同時並行で複数の国際共同試験を実施することでアジア全体における早期薬剤開発を推進することである。本事業ではマレーシア、タイ、フィリピン、インドネシア、ベトナムを中心にソフト面での教育研究等の支援とハード面での治験実施基盤整備、そして複数の国際共同研究の実施を並行して行う。今後の展開として、本事業で整備するアジアがん臨床試験ネットワークの枠組みを活用して、アジア地域で国際共同試験を常時5試験以上実施する体制構築を目指し、製薬企業、CRO、患者団体、アカデミアといったstakeholdersの参画を世界的に呼びかけていく。

The National Cancer Center Hospital (NCCH) has launched ATLAS (Asian clinical Trials network for cAnCerS) project since September 2020 supported by AMED. The project aims to establish a clinical research network across Asia as a framework for international clinical trials and to stimulate early oncology drug development in the region by conducting several international trials in parallel. We will work together with collaborators from Malaysia, Thailand, Philippines Indonesia, and Viet Nam to run multiple international collaborative research projects as well as to build capacity through training programs and infrastructure for clinical trials set up. As for future perspective on ATLAS project, NCCH plans to establish so robust network that we can conduct a minimum of five international trials at all times and to encourage pharmaceutical companies, CROs, patient advocates, academia, and all the global stakeholders to participate in the project.

Purpose: ATLAS project

- Purpose
 - To establish Asian Cancer Trials Network
 - Facilitate early drug development and genomic medicine together with Asian countries
 - To conduct multiple international trials under the ATLAS project
 - Initially focus on academic clinical trials
 - Encourage industries to utilize the ATLAS network
- A part of governmental policy on UHC in Asia
 - Promote regulatory harmonization
 - Establish the infrastructure for clinical trials



Reinforcement of clinical trials infrastructure & network

- Building clinical trials network between Japan & ASEAN countries
 - ~15 hospitals from Malaysia, Thailand, Vietnam, Indonesia, Philippines
- Reinforcement of infrastructure for clinical trials
 - Increase full-time clinical research coordinators (CRCs), investigators, molecular scientists etc.
 - Purchase equipment: refrigerators, deep freezers, centrifugal separators, ECGs, bedside monitors etc.
 - Guide to obtain ISO15189 certification
- Requirement for the sites
 - Enroll patients to collaborative clinical trials
 - Assign liaison officers (physician/administrative) for the network
 - Join the capacity building programs under this project

Human exchange thru capacity building program

- Capacity building programs based on local needs
 - High-quality cancer clinical trials program
 - Essential knowledge for clinical trial support
 - On-the-job training by the CRC section at NCCH
 - Cancer genome-based medicine program
 - Sampling, DNA/RNA extraction, target sequencing, cancer genome profiling, storage & analysis of genomic information, expert panel, reporting etc.
 - Quality assurance of laboratory (ISO15189)
 - Phase 1 trials development program
 - On-site training in the Department of Experimental Therapeutics at NCCH

International clinical trials

- Constantly perform >=5 academic trials under the network
 - NCC will negotiate with industries and share the study drug & funding with ASEAN sites
 - Study drugs will be given for free
 - Research funding will be shared
 - Investigators from the participating sites can propose study idea
 - Most trials focus on unapproved/off-label drugs to obtain/expand drug indication
 - Molecular targeted/immune oncology drugs
 - Improve drug access for local patients
- Multiple clinical researches under preparation
 1. A-TRAIN study
 2. TEAL trial
 3. MASTER KEY Asia

Establish Asian clinical trial network & promote genomic medicine across Asia

