



National Cancer Center Japan

Collaboration with PMDA Asia Office in the ATLAS project

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National Cancer Center Hospital

- Japan's No. 1 flagship hospital in oncology
 - Located at the center of Tokyo
 - Newsweek's "World's Best Specialized Hospitals 2024"
- N of beds, 578
 - 356 Staff Doctors, 178 Resident Doctors
712 Nurses (April 2023)
- Outpatients
 - 1,550 patients/day (new/returning)
 - Outpatient chemotherapy center
 - 203 patients/day (69 beds)
- Inpatients
 - 17 operation rooms
 - 5,503 operations per year
 - Advanced endoscopic surgery for early gastric cancer
 - Hospital-based clinical trials and research



NCC hospital @Tsukiji, Tokyo



Cyber Knife



Endoscopy
therapeutic room
Built-in wiring
ceiling system



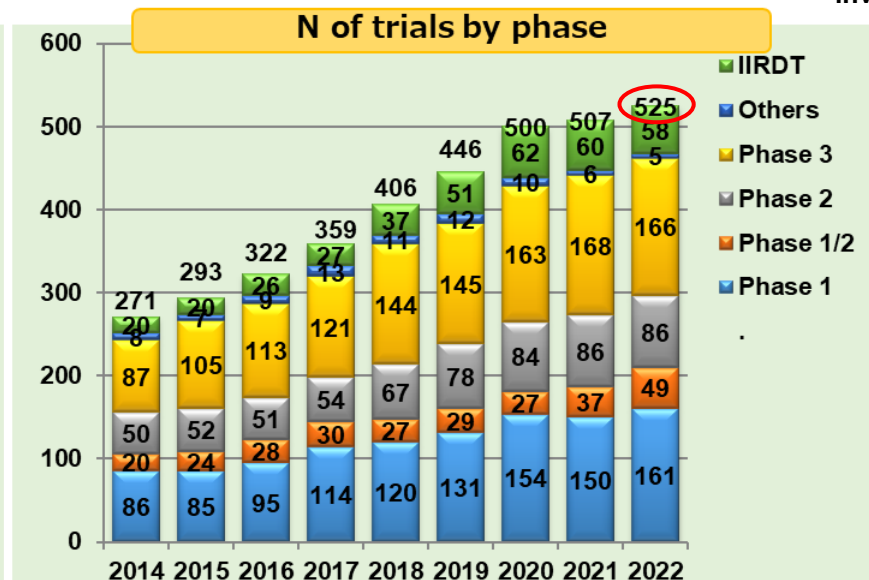
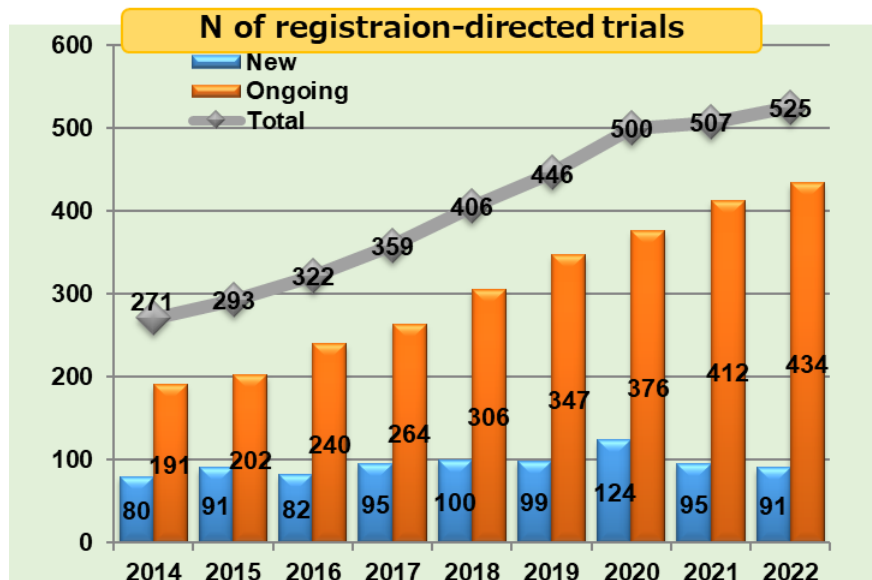
| | RANK | HOSPITAL |
|----|----------|--|
| 1 | Oncology | MD Anderson Cancer Center |
| 2 | Oncology | Memorial Sloan Kettering Cancer Ce |
| 3 | Oncology | Mayo Clinic - Rochester |
| 4 | Oncology | Gustave Roussy |
| 5 | Oncology | Samsung Medical Center |
| 6 | Oncology | Asan Medical Center |
| 7 | Oncology | The Royal Marsden Hospital - Londo |
| 8 | Oncology | Dana-Farber Cancer Institute |
| 9 | Oncology | Seoul National University Hospital |
| 10 | Oncology | The Johns Hopkins Hospital |
| 11 | Oncology | Charité - Universitätsmedizin Berlin |
| 12 | Oncology | Massachusetts General Hospital |
| 13 | Oncology | The Princess Margaret Cancer Centr |
| 14 | Oncology | Peter MacCallum Cancer Centre |
| 15 | Oncology | <u>National Cancer Center Hospital</u> |



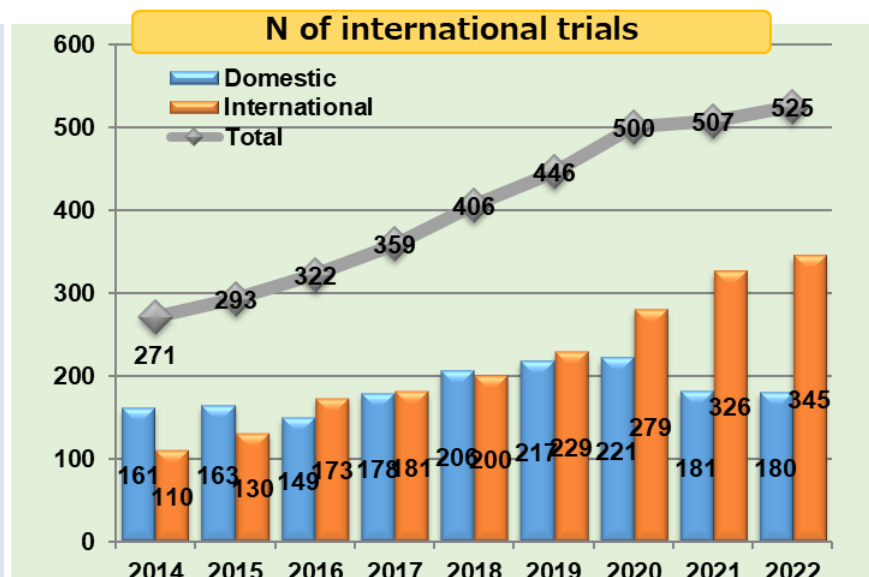
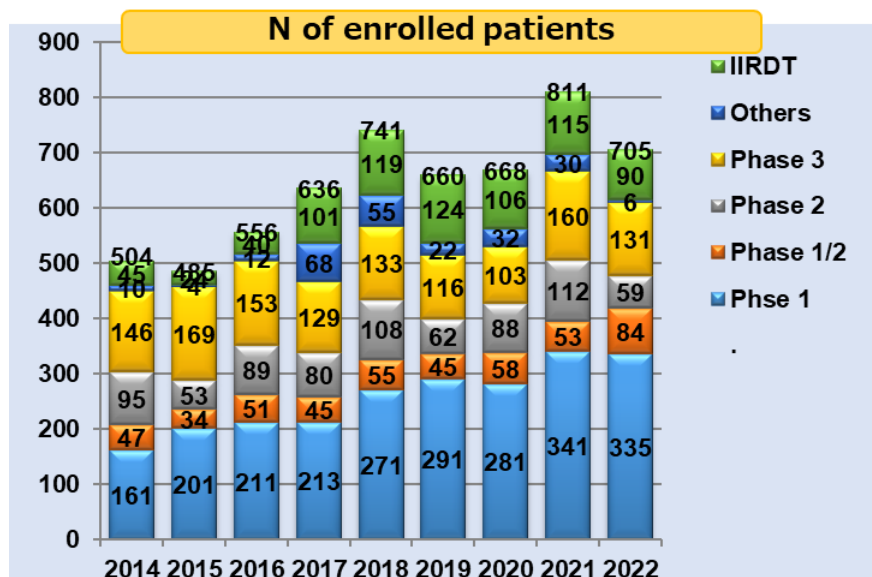
Out-patient Treatment Center 2

Number of registrational trials (Chicken)* at NCCH

* Clinical trials aimed at regulatory submission to PMDA using investigational new drug/device



** IIRDT: investigator-initiated registration-directed trial

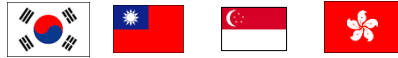


◆ There are about 300 pure academic clinical trials in addition to these IND trials

ATLAS: Asian clinical TriaLs network for cAncerS

Since Sep 2020

Existing networks with Korea, Taiwan, Singapore, China (HK)



Establish and expand the Asian Cancer Trials Network and facilitate early drug development and genomic medicine together with Asian countries

Expansion to ASEAN countries including Thailand, Malaysia, Philippines, Vietnam, Indonesia (~~45~~ >30 hospitals/institutions)



Strength in Asian networks:

- Population growth, economic development, aging society - increase of cancer patients, more needs for high-level treatment
- Little ethnic differences - genetics, physiques ...
- Reasonable cost in conducting clinical trials
- Area-specific cancers
 - liver, heat & neck, stomach, cervical, biliary etc.



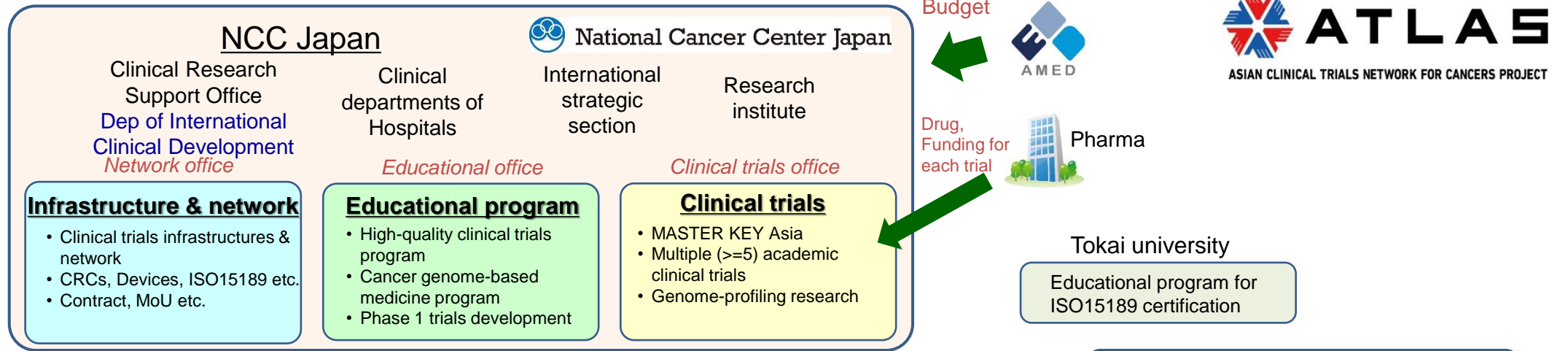
ATLAS project

- Building infrastructure & clinical trials networks
- Capacity building programs
 - clinical trial procedure & genomic cancer medicine
- International clinical trials under ATLAS
 - MASTER KEY Asia, A-TRAIN study etc.



Goals of ATLAS:

- Establish the infrastructure for clinical trials in Asia
- Introduce genome-based medicine in Asian
- Obtain/expand drug indication simultaneously in Asia promoting regulatory harmonization with PMDA



- Provide budget for clinical trials infrastructure
- Offer educational opportunity
- Propose & coordinate multiple clinical trials



- Patient accrual for clinical trials under the network (MASTER KEY Asia, academic clinical trials)
- Join the network meeting/ educational program

Asian Cancer Trials Network

NCC Asia Office (Bangkok)



ATLAS board members



President

Dr Kan Yonemori
(Japan)



President elect

Dr Darren Lim Wan
Teck (Singapore)



Director, ATLAS HQ

Dr Kenichi Nakamura
(Japan)



Malaysia

Dr Voon Pei Jye
Dr Wan Zamaniah



Philippine

Dr Marcelo Severino Imasa
Dr Jose Jasper Andal



Thailand

Dr Ekaphop Sirachainan
Dr Charuwan Akewanlop



Vietnam

Dr Dang Huy Quoc Thinh
Dr Dao Van Tu



Taiwan

Dr Ming-huang Chen
Dr Tom Wei-Wu Chen



Korea

Dr Joohyuk Sohn
Dr Wonyoung Choi



Singapore

Dr Darren Lim Wan Teck
Dr David SP Tan
(Dr Yoon-Sim Yap)



Japan

Dr Hidehito Horinouchi
Dr Ken Kato

NCC Asian Partnerships Office @Bangkok

■ Purpose of APO

- Strengthen local ARO function for Asian international trials
- Reinforce local site management & on-site monitoring function
- Reduce costs and achieve low-cost Asian collaborative studies
- Strengthen network with facilities, regulators, government, etc.



APO has been established at Bangkok since Nov 2021



PATHWAY trial

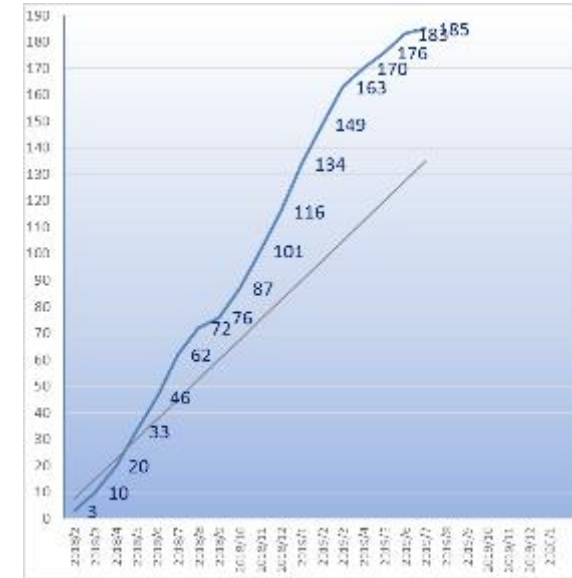
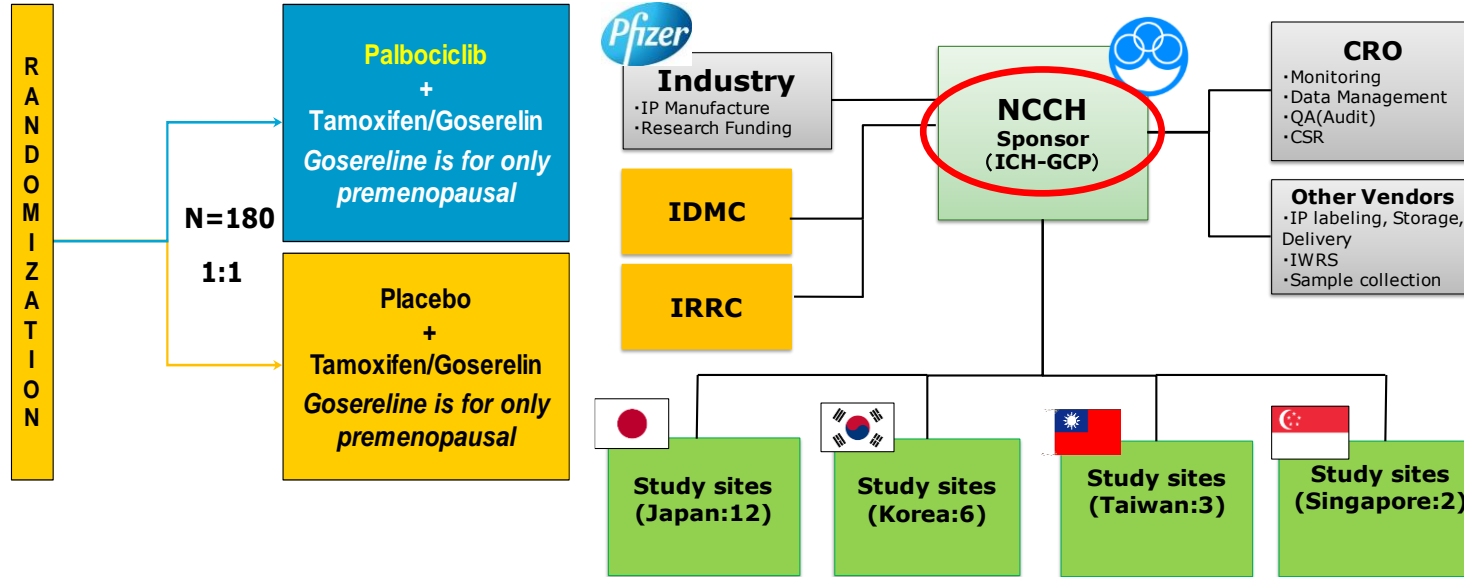
Asian Collaborative Investigator-initiated Registration-Directed Trial (Chicken) for Advanced Breast Cancer

Patient Population

- N = 180
(138 PFS events)
- HR+ HER2-
pre/peri and post-
menopausal locally
advanced or
metastatic
1st or 2nd line BC

Endpoints

PE: PFS
SEs: OS, OR, DR, CBR,
PK/PD/PGx, Safety



Planned accrual, 24 months



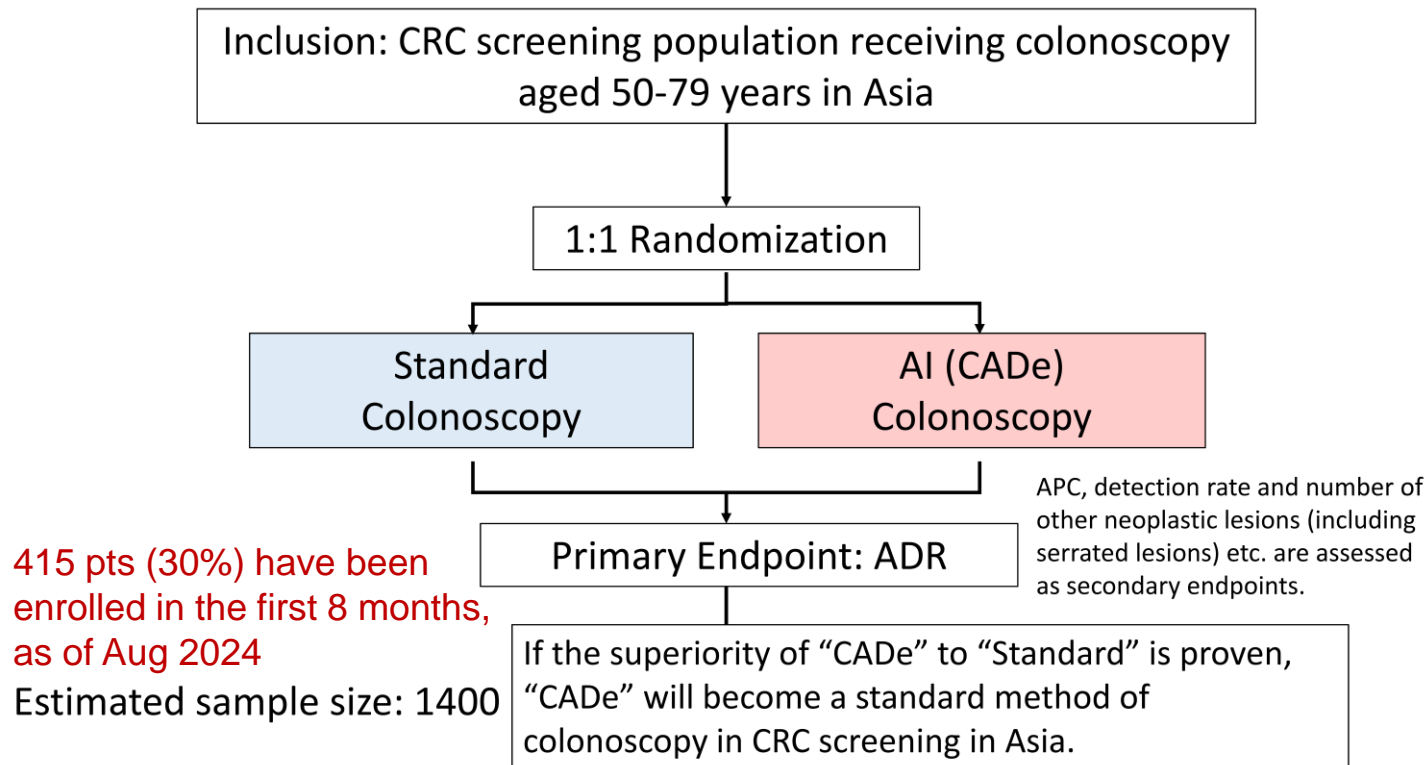
Completed in 18 months

Actual accrual

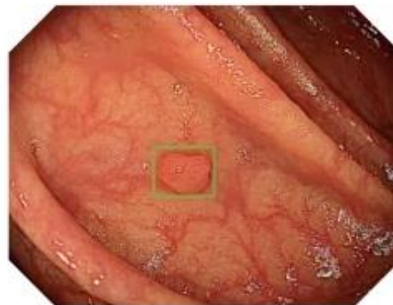
Japan 118
Korea 31
Taiwan 25
Singapore 11

- ✓ Japanese Academia-initiated, GCP-compliant, Placebo, Double-blind, Randomized Phase III trial
- ✓ National Cancer Center Hospital serves as the Sponsor under ICH-GCP
- ✓ Pfizer provides study drug and research funding
- ✓ Primary analysis revealed that the addition of Palbociclib prolonged PFS
- ✓ Drug indication of Palbociclib was expanded in Japan (Jan 2024)
- ✓ Regulatory application has been made even in other countries

Project CAD (randomized phase III trial)



White Light



ENDO-AID CAdE
with marker

- ◆ This Asian collaborative trial will investigate whether AI diagnostic support tool for colonoscopy (CAdE) is superior in adenoma detection rate compared to standard colonoscopy for colorectal cancer screening program
- ◆ Participating countries include Japan, South Korea, Taiwan, China (Hong Kong), Thailand and Singapore.
- ◆ This trial will contribute to the establishment of a better standard diagnostic procedure across Asia and is expected to have a significant impact on the community of endoscopists.

(Clinical Trial Registry: jRCT 1032230396)

Collaboration with PMDA Asia Office

■ Goals of the ATLAS project

- ❑ Establishment of a clinical trial network of Asia, by Asia, for Asia
- ❑ Develop better treatments for Asian cancer patients in collaboration with Asian institutions & regulatory authorities

■ Potential collaboration with PMDA Asia Office

- ❑ Joint visits to ATLAS sites and regulatory authorities in Asian countries
- ❑ Mutual participation in each other's capacity-building programs
- ❑ Promoting personnel exchange using respective networks
- ❑ Regular information exchange meetings with participants from industry, regulatory authorities, and academia etc.

Thank you!



*Change the world better through clinical trials,
together !*