

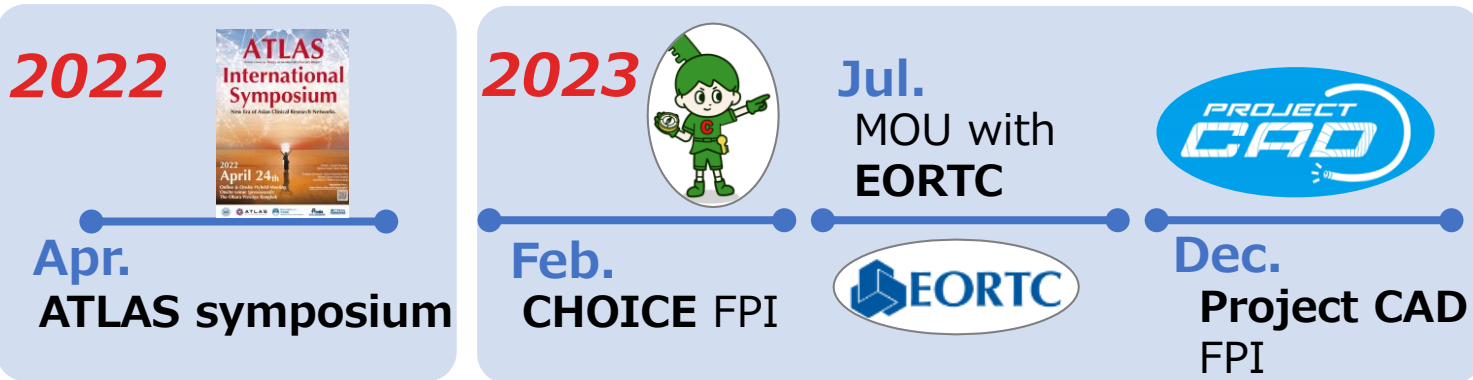


International Symposium for Asia Regulatory
Coordination
~Memorial for Establishment of PMDA Asia Office~
29th August 2024

ATLAS and cooperation with Regulatory Authorities

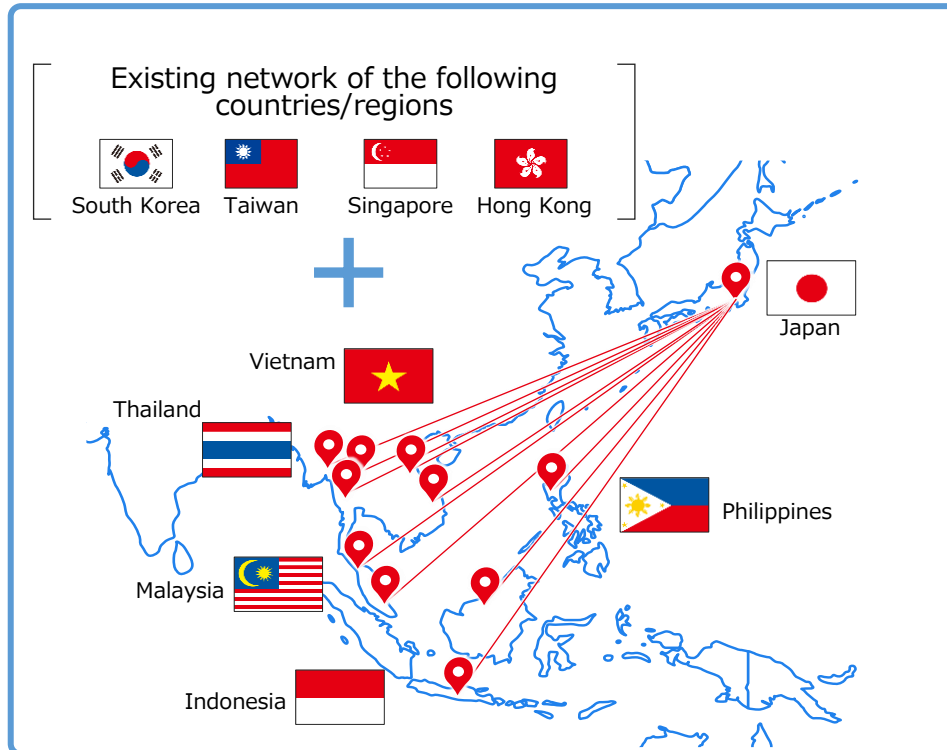
Mitsumi TERADA MD, PhD
General Manager, Asian Partnerships Office
National Cancer Center Hospital JAPAN

Asian Clinical Trials Network for Cancers



Objectives

- Establish a platform for international clinical trials in Asia
- Harmonize regulations across Asia
- Promote genomic medicine in Asia
- Improve drug access in Asian countries

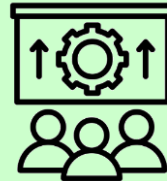


ATLAS HQ (NCCH)

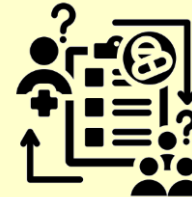
Infrastructure & network



Educational program



Clinical trials

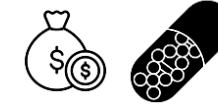


Tokai university

Educational program for ISO15189 certification



Budget



Drug,
Funding for
each trial



Pharma

Japan

Clinical Research Core

Medical e



Human res



E-learning site:



✓ Some more Eng
contents are pu
under preparat

Active

Preparing

Study	Cancer type	Japan	Korea	Taiwan	Singapore	Thai	Malaysia	Philippines	Vietnam	China	Indonesia	India
PATHWAY	Breast	◎	◎	◎	◎							
MASTER KEY Asia	Rare	◎	◎	◎		◎	◎	◎	◎		△	△
A-TRAIN	6 cancers	◎	◎	◎	◎	◎	◎	◎	◎			
HARMONY	Breast	◎						◎				
CHOICE	Biliary	◎		◎		◎	◎	◎				
Project CAD	Colorectal	◎	○	○	○	○				○		
Cryo-RCT	Lung	○		△	△		△					
P-SBRT	Pancreas	○	○	○								

※ interventional study

◎ : activated, ○ : under preparation, △ : under planning

Asian Clinical Trials as ATLAS

PATHWAY

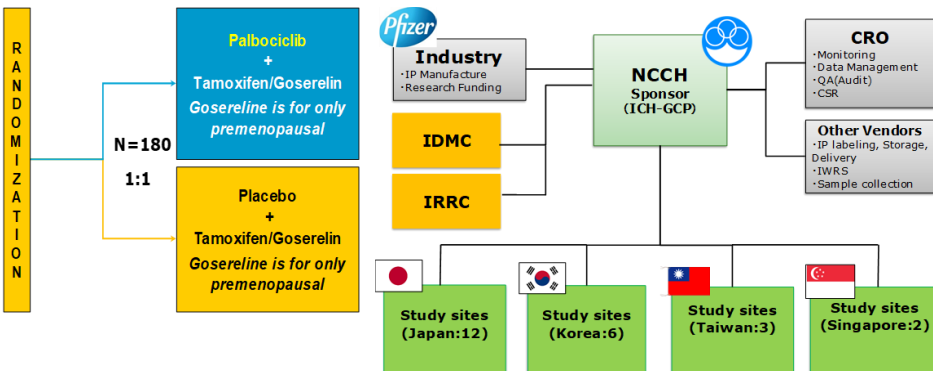
Asian Collaborative Investigator-initiated Registration-Directed Trial for Advanced Breast Cancer

Patient Population

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

Endpoints

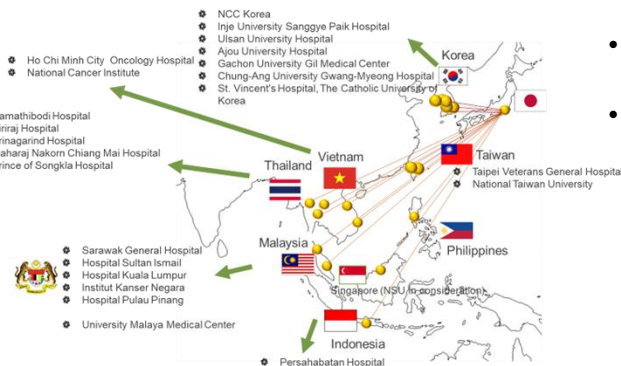
PE: PFS
SEs: OS, OR, DR, CBR, PK/PD/Pgx, Safety



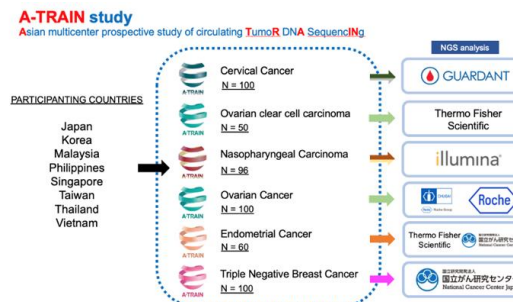
MASTER KEY ASIA

Asian Collaborative prospective registry study for rare cancer

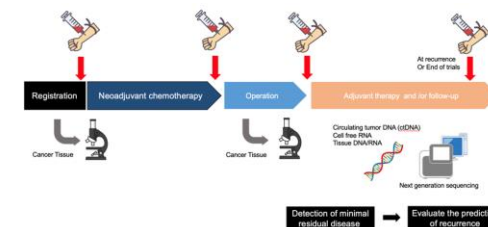
- Comprehensive clinical/genomic database in Asia
- Central path review, NGS analyses & reporting
- International tumor board between NCC & sites



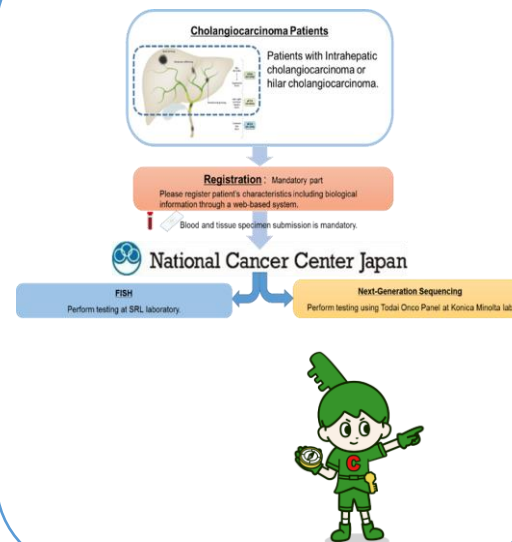
ATRAN



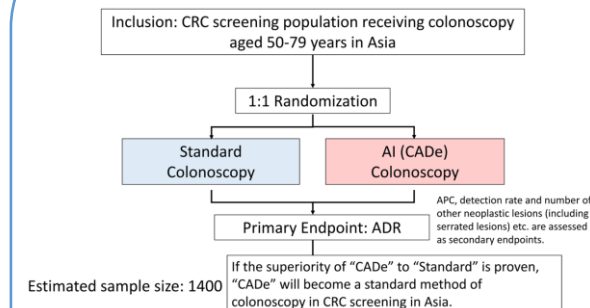
HARMONY



CHOICE

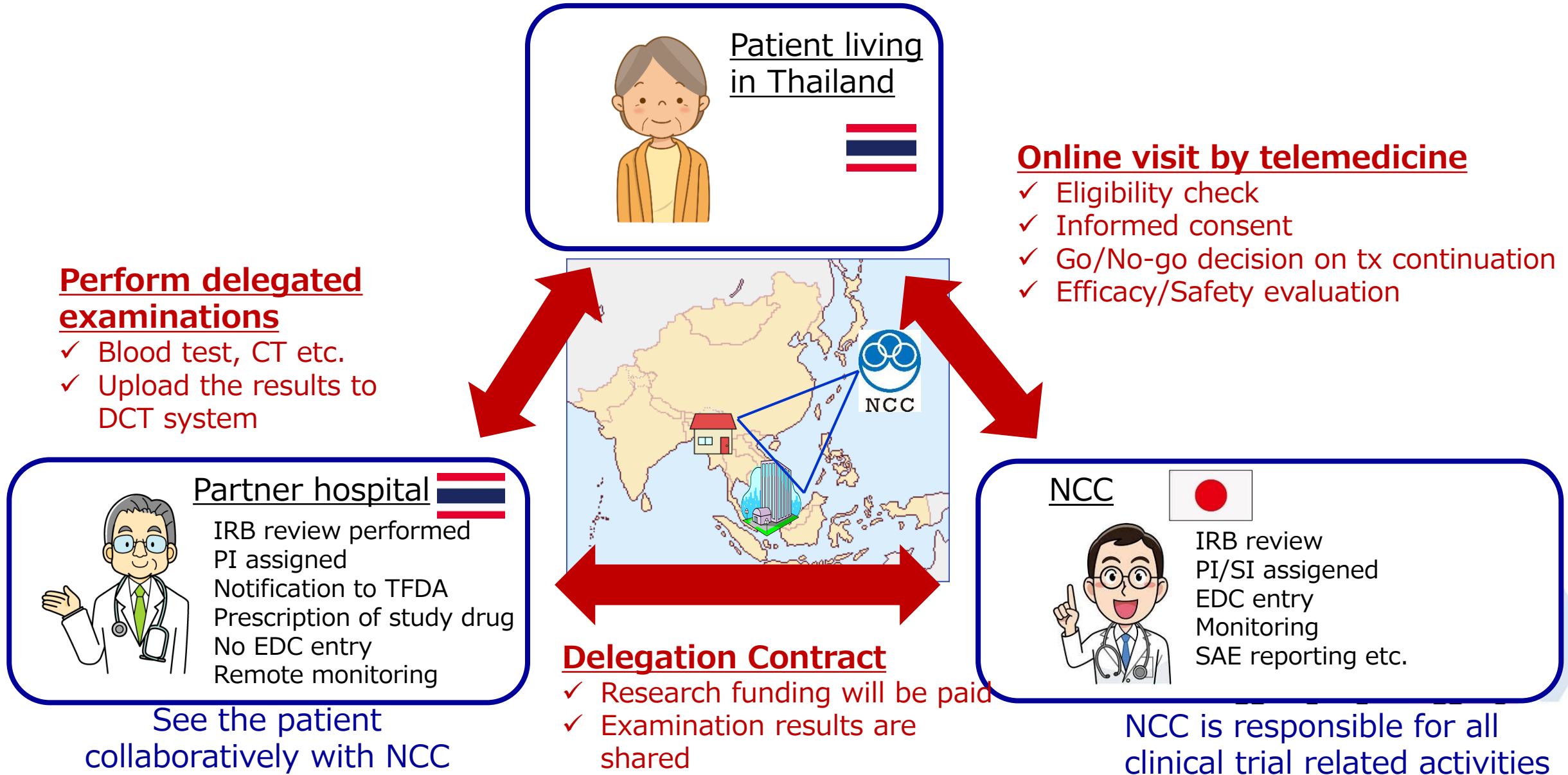


Project CAD

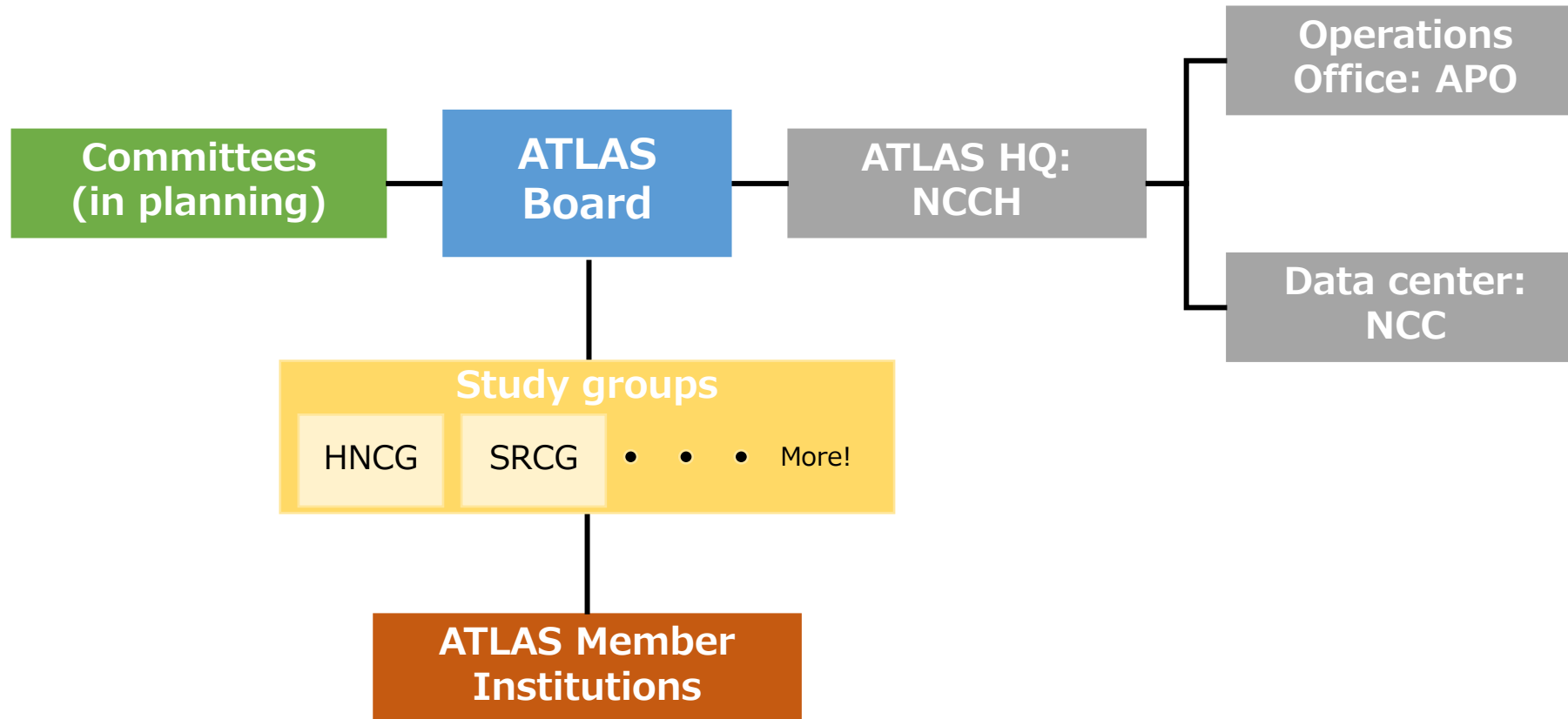


Number of enrolled patients since ATLAS initiation	MKA+CHOICE (as of July 2024)	HARMONY (as of Aug. 2024)	ATRAIN (as of April 2024)	Project CAD (as of July 2024)	Total
National Cancer Center Hospital (JP)	-	26	105	149	280
Hospital Pulau Pinang (MY)	115	-	-	-	115
King Chulalongkorn Memorial Hospital (TH)	-	-	5	97	102
Institut Kanser Negara (MY)	78	-	19	-	97
Sarawak General Hospital (MY)	62	-	29	-	91
K Hospital (VN)	41	-	41	-	82
National Taiwan University Hospital(TW)	24	-	53	0	77
National Cancer Center Korea (KR)	69	-	-	0	69
Jikei University Hospital (JP)	-	-	-	66	66
St. Luke's Medical Center (PH)	37	9	20	-	66
Hospital Sultan Ismail (MY)	64	-	-	-	64
Hospital Kuala Lumpur (MY)	49	-	12	-	61
University Malaya Medical Center (MY)	40	-	16	-	56
Toho University Omori Medical Center	-	-	-	50	50
Fu Jen Catholic University Hospital (TW)	-	-	-	39	39
Siriraj Hospital (TH)	25	-	9	-	34
Ho Chi Minh City Oncology Hospital (VN)	-	-	31	-	31
Srinagarind Hospital (TH)	26	-	-	-	26
Ramathibodi Hospital (TH)	17	-	9	-	26
Taipei Veterans General Hospotal (TW)	23	-	-	-	23
National Cancer Centre Singapore (SG)	-	-	17	0	17
National University Hospital (SG)	-	-	16	0	16
CHA Bundang Medical Center (KR)	15	-	-	-	15
Pusan National University Hospital (KR)	11	-	-	-	11
Maharaj Nakorn Chiang Mai Hospital (TH)	9	-	1	-	10
The Chinese University of Hong Kong Prince of Wales Hospital (CN)	-	-	-	9	9
Prince of Sonkla University Hospital (TH)	8	-	0	-	8
Vajira Hospital (TH)	-	-	7	-	7
Ulsan University Hospital (KR)	6	-	-	-	6
National Cancer Center Hospital East (JP)	-	-	-	5	5
The Catholic Univ of Korea St. Vincent's Hospital (KR)	5	-	-	-	5
Phramongkutklao Hospital (TH)	-	-	4	-	4
Sanggye Paik Hospital (KR)	2	-	-	-	2
Chung-Ang University Hospital (KR)	2	-	-	-	2
Severance Hospital Yonsei University Health System (KR)	-	-	1	-	1
Yonsei University Wonju College of Medicine (KR)	-	-	-	0	0
CUHK Medical Centre (CN)	-	-	-	0	0
	728	35	395	415	1573

Decentralized Clinical Trial: New challenge



Good Governance and study groups for further trials.



ATLAS Board members



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(Japan)



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Dr Darren Lim Wan
Teck (Singapore)



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		Dr Yoon-Sim Yap	National Cancer Centre Singapore
	Japan	Dr. Ken Kato	National Cancer Center Japan
		Dr. Hidehito HORINOCHI	National Cancer Center Japan
Top 5 sites in 2024	Japan	Dr. Hitomi Okuma	National Cancer Center Japan
	Malaysia	Dr Lee Fong Wan	Hospital Pulau Pinang
	Malaysia	Dr. Lim Yueh Ni	Sarawak General Hospital
	Malaysia	Dr. Suhana Binti Yusak	Institut Kanser Negara
Elected members	Taiwan	Dr. Tsung-Hao Liu	National Taiwan University Hospital
	Japan	Ms. Tomomi Hata	National Cancer Center Japan
	Japan	Dr. Kazuki Sudo	National Cancer Center Japan
	Japan	Dr. Mitsumi Terada	National Cancer Center Japan

ATLAS Sarcoma and Rare Cancer Group



Chair

Dr. Tom Wei-Wu Chen
(National Taiwan University Hospital)



Secretary

Dr. Hitomi Okuma
(National Cancer Center Japan)

Group members

Steering committee	Taiwan	Dr. Chueh-Chuan Yen	Medical Oncology	Taipei Veterans General Hospital
	Malaysia	Dr Rozita Abdul Malik	Clinical Oncologist	University of Malaya Medical Center
	Malaysia	Dr. Lee Fong Wan	Pathologist	Penang General Hospital
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	Malaysia	Dr Lee Cheen Leng	Clinical Oncologist	Penang General Hospital
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	Malaysia	Dr. Syafirin bin Abdullah Sani	Clinical Oncologist	Institut Kanser Negara
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	Singapore	Dr Anand Jeyasekharan	Medical Oncology	National University Cancer Institute, Singapore
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	Philippine	Dr Mel Valerie Ordinario	Medical Oncology	St. Luke's Medical Center
	Philippine	Dr. Jose Jasper Andal	Pathologist	St. Luke's Medical Center
	Thailand	Dr. Touch Ativitavas	Medical Oncology	Ramathibodi Hospital
	Korea	Dr Tak Yun	Medical Oncology	National Cancer Center Korea
	Japan	Dr Akihiko Yoshida	Pathologist	National Cancer Center Hospital
	Japan	Dr Yuki Kojima	Medical Oncology	National Cancer Center Hospital
Operational office	Japan	Dr. Mitsumi Terada	Surgical Oncology	National Cancer Center Hospital
	Japan	Dr. Yuta Sekino	Radiation Oncology	National Cancer Center Hospital
	Japan	Ms. Arthitada Hanada		National Cancer Center Hospital

Steering

Scientif

Operati

ATLAS HNCG Meeting in Bangkok (25 July 2024)

Engagement of the U.S. EBP

- A detailed discussion regarding the potential Phase III clinical trial for head and neck cancer in Asia, currently under consideration by the company
- Coordination efforts have commenced with NCCH and a CRO to facilitate a PMDA consultation.

Participation of the Global EBP R&D Division Head

- Discussion on a drug approved by the US FDA, which the company is considering for expansion in head and neck cancers in Asia.
- Discussion on a bridging study for Japan and strategies for getting approval of the drug in Japan.
- Preparation for a Phase III trial in Pan-Asia, utilizing ATLAS network and infrastructure

Commencement of Enrollment for the Head and Neck Cancer Cohort in MKA

- Enroll additional 160 cases of head and neck cancers with NGS analysis planned
- Currently under ethical review, with patient enrollment anticipated to begin in September



How to collaborate with Regulatory Authorities

Cancer Medicines Forum (CMF)

- EMA runs a Cancer Medicines Forum since March 2022, aiming to help advance research into optimizing cancer treatments and foster high standards in cancer care in the European Union (EU).
- EMA co-chairs the forum with the European Organisation for Research and Treatment of Cancer (EORTC)
- Other members from academic organizations.
 - European Haematology Association (EHA)
 - European Society of Medical Oncology (ESMO)
 - European Society for Paediatric Oncology (SIOPE)
 - International Society of Geriatric Oncology (SIOG)
- Willingness of EMA to further engage with its academic stakeholders and support academia-driven research such as treatment optimization research.



Series of workshops or events organized by EMA and EORTC

- Discuss and share some specific topics from different perspectives and standpoints.
 - Treatment optimization research
 - PRO/QOL
 - Pragmatic trials

Expectations for Asian regulatory authorities

- Establishment of forum similar to the CMA in Europe, involving regulatory authorities and academia
 - Regular discussions between regulatory authorities and academic representatives on Asia-specific issues
 - Increasing more academic clinical trials
 - “Drug loss” problem
- Co-hosted events by ATLAS and regulatory authorities
 - Development of treatment for rare cancers and Asia-specific type of cancers
 - APO and PMDA Asia office can play major role for coordinating events.



Thank you for your attention.



Any questions?
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