

ARO Alliance for ASEAN & East Asia (ARISE)



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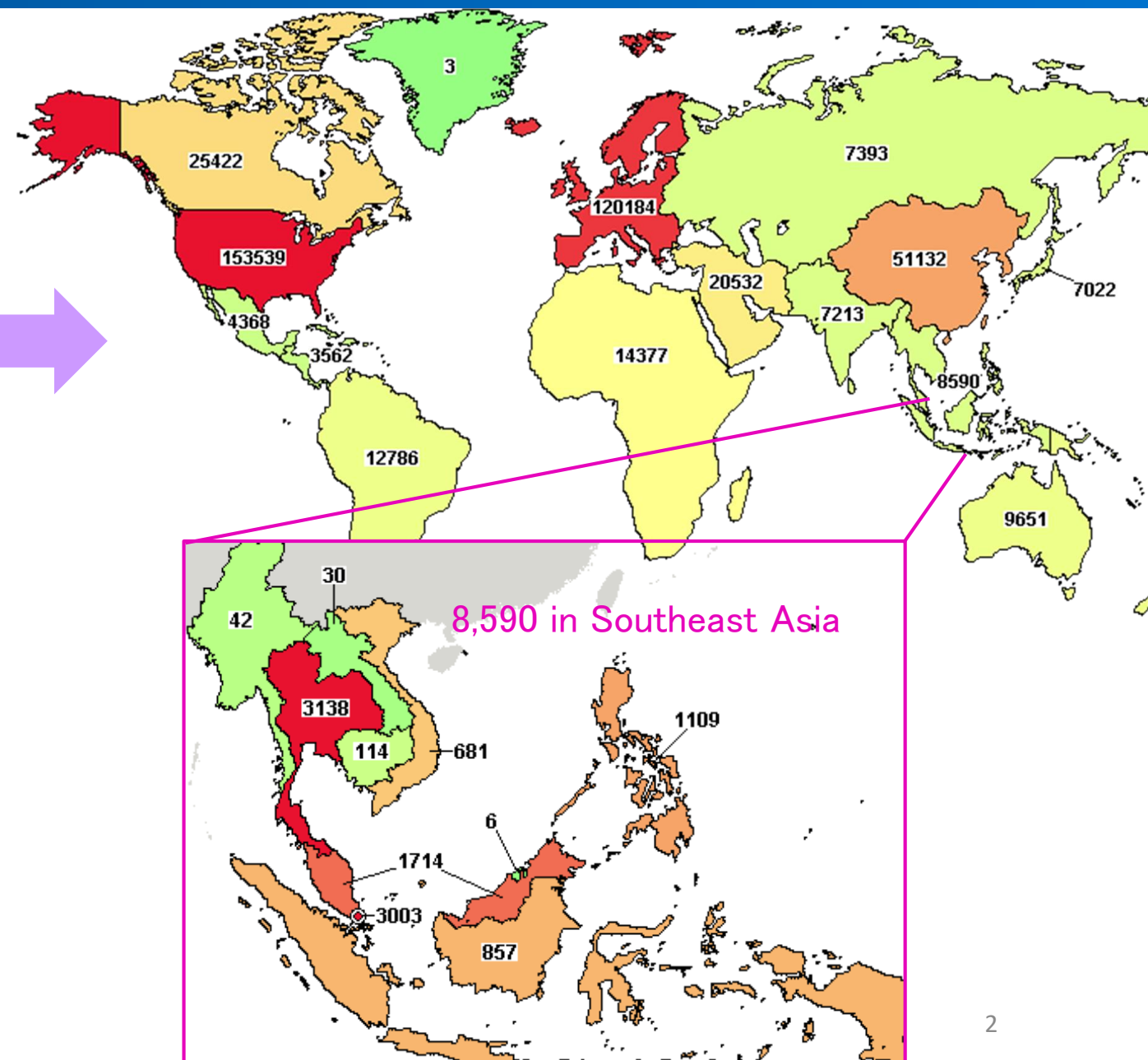
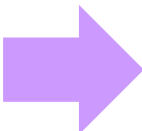
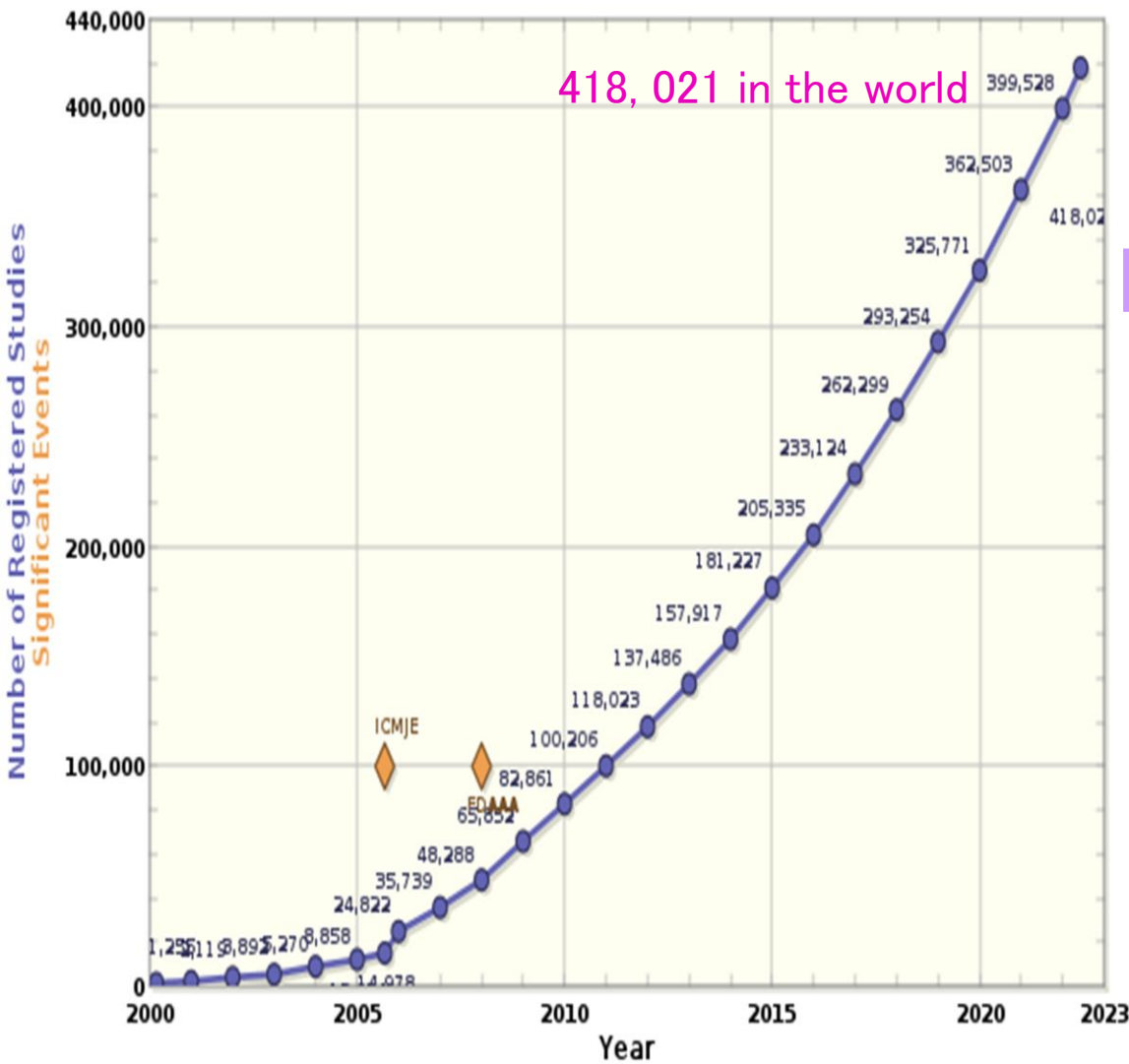
Center for Clinical Sciences

National Center for Global Health and Medicine

April 25, 2022

Background Information: No. of Registered Clinical Trials (as of June 09 2022)

Number of Registered Studies Over Time
and Some Significant Events (as of June 09, 2022)



What is **ARO Alliance for ASEAN & East Asia (ARISE)**?

Platform of Academic Research Organization (ARO) for Medical Innovation that jointly promote quality and quantity of clinical studies in the Asia region

Definition of the Academic Research Organization (ARO) (New Japan Scientific Glossary)

- Organizations that promote and support clinical trials in academia, including universities and research institutes
- Universities (academia) that conduct clinical trials by making use of their many specialties and characteristics

Japanese and APEC policies

❑ Japanese Government Policy & Initiatives

Japan Revitalization Strategy, Health and Medical Care Strategy, Asia-Africa Health Initiative, Task Force for the Promotion of Harmonization of International Regulations, International Pharmaceutical Partnership, Ministerial Conference on International Threats against Infectious Diseases, etc.

Government Departments:

- MHLW: Research and Development Division, International Affairs Division, Minister's Secretariat, Tuberculosis and Infectious Diseases Division, Medical Device Policy Office, Economic Affairs Division, etc
- Ministry of Foreign Affairs (MOFA) : General Affairs Division, National Land Insurance
- Ministry of Economy, Trade and Industry (METI): Asia Pacific Division, Trade Policy Bureau
- Cabinet Secretariat: Office of Health and Medical Strategy, International Coordination Office on Infectious Diseases

❑ The Asia-Pacific Economic Cooperation (APEC)

Life sciences innovation forum regulatory harmonization steering committee calls for promoting Multi-Regional Clinical Trials (MRCTs) so that new medicinal products rapidly become available to patients

Multinational cooperation in clinical researches is needed in Asia

To jointly address common global health issues

To make new medicinal products rapidly become available to patients



Establishing an Asian ARO Network

NCGM (National Center for Global Health and Medicine)

NCC (National Cancer Center)

undertake this mission

□ 成長戦略実行計画 2021 (令和3年6月18日閣議決定)

第13章 重要分野における取組 2. 医薬品産業の成長戦略: 国際共同治験の推進…を進める。

□ 「健康・医療戦略」(令和2年3月27日閣議決定、令和3年4月9日一部変更)

4. 健康長寿社会の形成に資する新産業創出及び国際展開の促進等、4.2.2 国際展開の促進

(基盤の整備) 単なる医療機器や医薬品の我が国からの供給にとどまらず、それらの研究開発、製造、流通、安全規制、適正使用等に求められる社会的基盤の整備を…推進する。

(規制調和の推進) 「アジア医薬品・医療機器規制調和グランドデザイン」(2019年6月20日推進本部決定)に基づき、アジアにおける医薬品、医療機器等のアクセス向上に向け、厚生労働省・PMDAと海外当局との協力関係の強化、アジアにおける臨床研究・治験のネットワークを構築するための拠点整備及び人材の育成を行うこと等によりアジア各国との規制調和を推進する。

□ ワクチン開発・生産体制強化戦略(令和3年6月1日閣議決定)

2. ワクチンの迅速な開発・供給を可能にする体制の構築のために必要な政策、2.3 治験環境の整備・拡充

海外の環境整備として、アジア地域における臨床研究・治験ネットワークを充実させるとともに、平時から、海外で流行する感染症に対するワクチンの治験実施促進などに取り組む。具体的には、日本発の国際共同治験が迅速に実施可能となるよう、アジア地域の拠点医療機関において国際標準(ICH-GCP)の治験実施基盤を整備し、

□ 「アジア医薬品・医療機器規制調和グランドデザイン」実行戦略(令和2年7月14日健康・医療戦略推進本部決定)

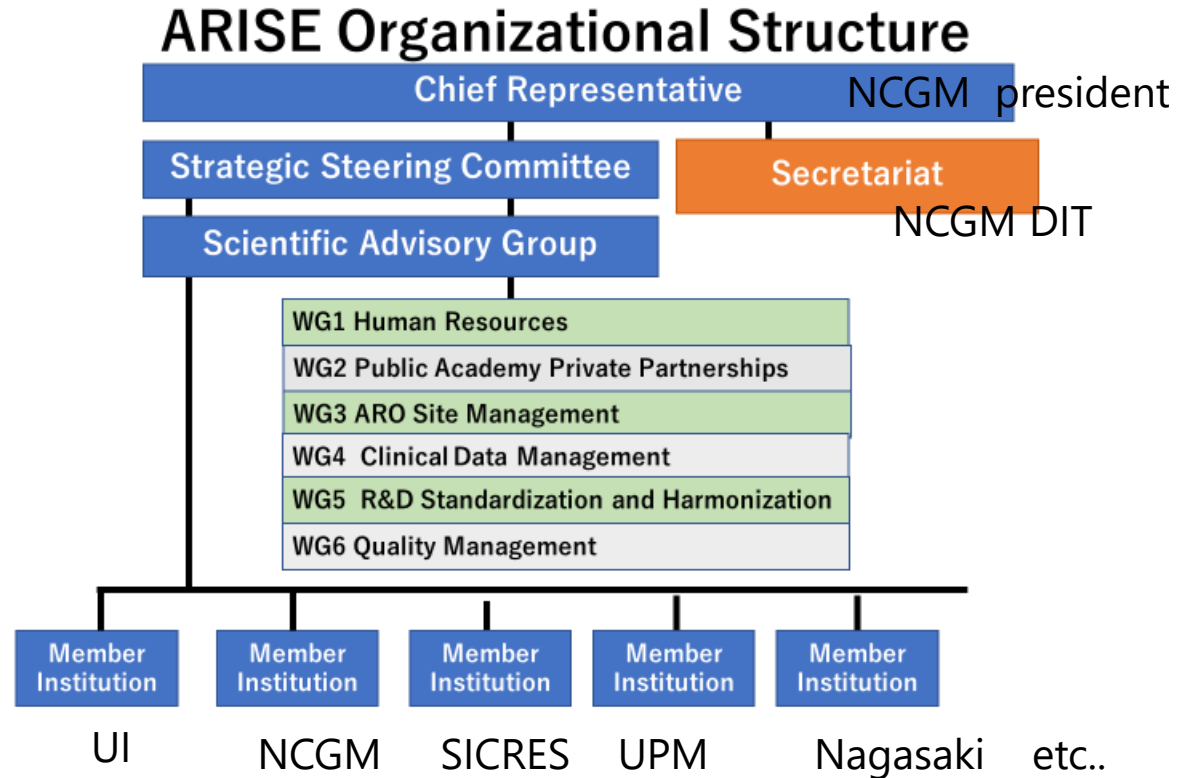
3. 臨床開発体制の充実に向けた取り組み

～臨床試験実施拠点のネットワークをアジア圏で構築することは、医薬品・医療機器開発を迅速かつ低コストで実施することにつながる。～

国立国際医療研究センター(NCGM)等の既存の事業を活用・強化し、各国の状況に応じた治験・臨床研究実施施設の選定や現地協力事務所を設置・強化する

ORGANIZATIONAL STRUCTURE

- ❑ The **Chief Representative** is responsible for the overall leadership and management of the ARISE's operational and administrative functions.
- ❑ The **Strategic Steering Committee** advises on the strategic direction of the ARISE. The committee comprises representatives of each member institution.
- ❑ The **Scientific Advisory Group** oversees responsibility for the scientific direction of the ARISE network. The Scientific Advisory Committee comprises senior investigators of each member institution.
- ❑ Thematic **Working Groups** are a pivotal mechanism in facilitating ongoing collaborations across sites and reflect some of the shared interests of investigators within the ARISE Research Network. The Working Groups comprise investigators and specialists of each member organization.
- ❑ The **Secretariat** executes, supports, coordinates, and facilitates the activities of the ARISE network. The secretariat comprises of a secretary-general and technical and administrative personnel of the organization.



Scope of ARISE Activities and WORKING GROUPS

Member organization shall work on the following activities to achieve missions of the ARISE:

- (1) Explore possibilities for research collaborations and conduct multicenter-clinical studies
- (2) Discuss, share information, make recommendations and publish reports and articles.
- (3) Organize trainings, joint conferences, symposia, and other scientific meetings on subjects of mutual interest.
- (4) Exchange regulatory information and cooperate with regulatory authorities.
- (5) Standardize basic international operation scheme, SOPs, and administration
- (6) Explore possibilities for any other cooperative activities to which member organizations agree.

6 Working groups

1. WG1: Human Resources (HR)
2. WG2: Public-Academic-Private-Partnerships (PAPPs)
3. WG3: ARO site management
4. WG4: Clinical Data Management
5. WG5: R&D Standardization and Harmonization
6. WG6: Quality Management

Necessary commitment from member organization

- Nomination of persons in charge
- Attendance to (web-based) meetings and paper works
e.g. Board: Annually~
 WGs: Monthly~
- Cooperate in clinical studies (as per separate agreement)

※ When conducting joint clinical study among member institutes, other research contracts shall be concluded as necessary.

GOAL: Promoting Medical Advancement by multicenter clinical studies

Initial stage of the establishment

- Investigator initiated & multicenter-clinical trials
- Studies of Japanese products
- Focusing on essential medical products in Global Health field

motivation of the Japan side



In the future

- Promote researches to generate EBM
- Studies of non-Japanese products
- Expanding to cutting-edge techs to address emerging health needs

International mutual cooperation

VISION

ARISE contributes to enhancing health and reducing illness and disability by promoting a network of AROs in the Asian region.

MISSION

ARISE strives to achieve the following missions through efficient and effective collaboration with member organizations and stakeholders.

- 3.1 Promotes the integrity, safety, ethics, and quality of investigator-initiated clinical studies.
- 3.2 Contributes to developing innovative medical products to address unmet health needs and diseases of public health significance in the region.
- 3.3 Contributes to improving the resources and capacity of clinical study sites in the region.
- 3.4 Accelerates clinical studies and improves timelines and processes for authorization.
- 3.5 Promotes Public-Academic-Private-Partnerships (PAPPs) in the region.
- 3.6 Bridges the gap between sciences and policy for health.

ARISE Members

Country	Network expansion plan			Member Organization	NCGM Co-office
	Initial Term (2021-)	2nd Term (2022-)	3rd Term (2023-)		
Japan	●			National Center for Global Health and Medicine	
	○			Nagasaki University	
	○			Osaka University	
Indonesia	●			University of Indonesia	
	○			Mochtar Riady Institute	
Thailand	●			Faculty of Medicine Siriraj Hospital, Mahidol University	
Philippines	●			University of the Philippines Manila	
	○			Manila Doctors Hospital	
	○			Corazon Locsin Montelibano Memorial Regional Hospital	
Vietnam	●			National Bach Mai Hospital	
Malaysia		●		Clinical Research Malaysia	
Cambodia			●	TBD	
Lao P.D.R			●	TBD	
Myanmar			●	TBD	

Representatives of ARISE and PMDA



Dr. Norihiro KOKUDO
President,
National Center for Global Health and
Medicine (NCGM)



Dr. Yasuhiro FUJIWARA
Chief Executive,
Pharmaceuticals and Medical Devices
Agency (PMDA)



Assoc. Prof. Dao Xuan Co
Acting Director,
Bach Mai Hospital (BMH), Vietnam



Prof. Prasit Watanapa
Dean, Faculty of Medicine Siriraj
Hospital (FMSH),
Mahidol University, Thailand



Dr. Wawalum Arozal
Director,
Department of Pharmacology and
Therapeutic Pro Clinic, University
of Indonesia (UI)



Dr. Eva Maria Cutiongco-de la Paz
Director, National Institute of
Health,
The University of the Philippines
Manila (UPM)



Prof. Hiroaki Shimokawa
Vice Dean, Graduate School,
International University of Health
and Welfare (IUHW)



Prof. Dr. Irawan Yusuf
President,
Mochtar Riady Institute for
Nanotechnology (MIRIN)



Prof. Kenji Hirayama
School of Tropical Medicine and
Global Health,
Nagasaki University



Prof. Ken Nakata
Director, Center for Global Health,
Osaka University Hospital

Country	Member Organization	NCGM Co-office
Japan	National Center for Global Health and Medicine	
	Nagasaki University	
	Osaka University	
	International University of Health and Welfare	
Indonesia	University of Indonesia	○
	Mochtar Riady Institute	
Thailand	Faculty of Medicine Siriraj Hospital, Mahidol University	○
Philippines	University of the Philippines Manila	○
	Manila Doctors Hospital	
	Corazon Locsin Montelibano Memorial Regional Hospital	
Vietnam	National Bach Mai Hospital	○
Expected member country... Malaysia, India, Taiwan, Korea, Singapore, Myanmar, Cambodia, Laos and so on		

Partner global clinical networks & organizations

- ◆ Economic Research Institute for ASEAN and East Asia (ERIA)
- ◆ Harvard MRCT Center (Harvard Multi Regional Clinical Trials Center)
- ◆ Clinical Research Initiative for Global Health (CRIGH)
- ◆ Global Research Collaboration for Infectious Disease Preparedness (GloPIDR-R)
- ◆ European Clinical Research Infrastructure Network (ECRIN)
- ◆ Global Antibiotic Research & Development Partnership (GARDP)

Expected partners...

The European & Developing Countries Clinical Trials partnership (EDCTP)

Singapore Clinical Research Institute (SCRI)

Korea National Enterprise for Clinical Trial (KoNECT)

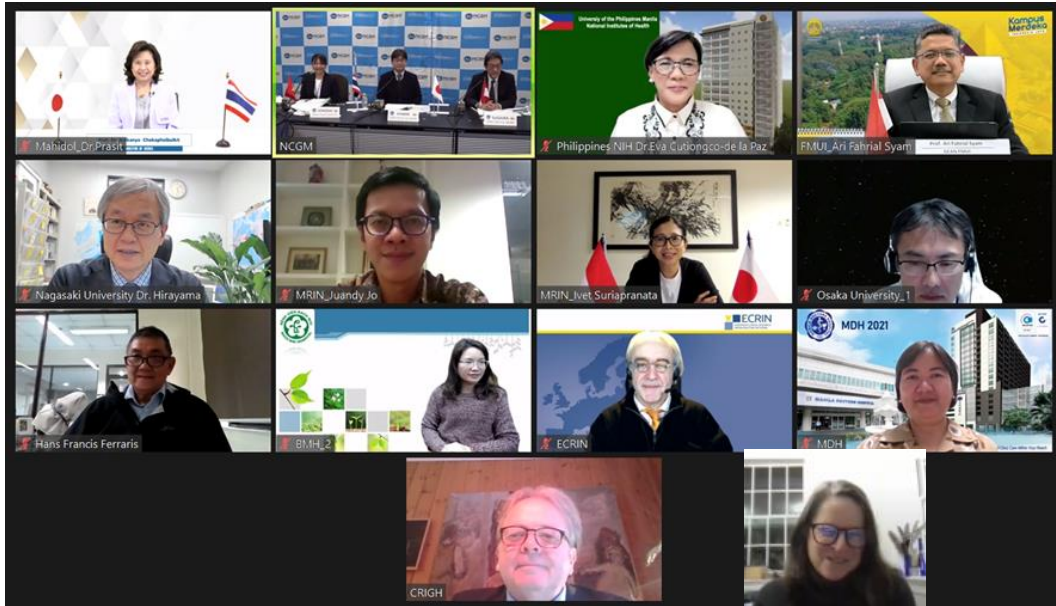
ARISE will strategically pursue partnerships with other research consortiums with a common interest and cooperate in mutually beneficial activities.

Examples of research consortiums and organizations to be partnered

- [Economic Research Institute for ASEAN and East Asia: ERIA](#)
- [Japan ARO Council](#)
- [Harvard MRCT Center \(Harvard Multi Regional Clinical Trials Center\)](#) →MOU with NCGM
- [Clinical Research Initiative for Global Health \(CRIGH\)](#) →Cooperation with ARISE through competency for clinical research specialist
- [Global Research Collaboration for Infectious Disease Preparedness \(GloPIDR-R\)](#) →Participate in the Clinical Trial Networks Working Group
- [European Clinical Research Infrastructure Network \(ECRIN\)](#)
- [The European & Developing Countries Clinical Trials partnership \(EDCTP\)](#)
- [Singapore Clinical Research Institute \(SCRI\)](#)
- [Korea National Enterprise for Clinical Trial \(KoNECT\)](#)

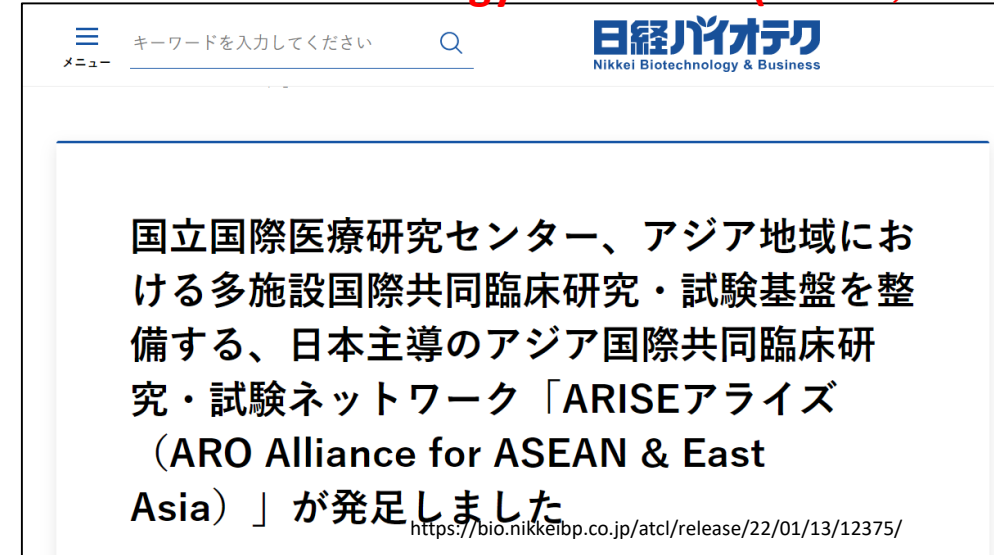
Launching of ARISE

～Kick off meeting (9th Dec, 2021)～



News articles in member countries

Nikkei Biotechnology & Business (13 Jan)



ANTARA NEWS.COM(Dec 31)

Indonesia, Japan ink MoU on solutions for global health problems

“We are not only building the foundation for ARISE by conducting the beneficial discussions but also all the institutions here can open the opportunity to collaborate for further elaborative projects.”

Depok (ANTARA) - The University of Indonesia (UI) and Japan's National Center for Global Health and Medicine (NCGM) signed a memorandum of understanding (MoU) on solutions for global health problems.

<https://en.antaranews.com/news/207197/indonesia-japan-ink-mou-on-solutions-for-global-health-problems>

NCGM's Clinical Research Portfolio in ARISE countries

as of Jan 31

Completed (1)

On-going (18)

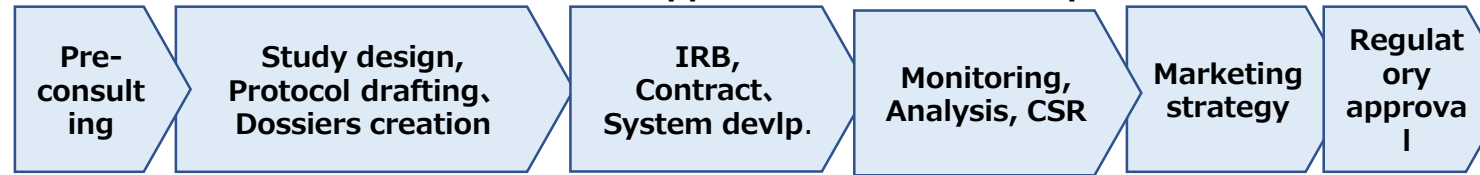
Under development (5)

Project name

Discussion and dialogue

Regulatory survey,
Market search,
Site feasibility,
R&D strategy

End-to end support from clinical trial phase to market



1. In vitro Antibiotic Susceptibility of Gram-negative Bacteria Isolated in VNM	2019年5月 (FPI) ~2019年12月 (LPO)	1,262/1,300	Publication
2. Evaluation of the New Malaria Diagnostic Device in THAI (LAMP Study)	2019年11月 (FPI) ~2022年8月 (LPO予定)	236/350	
3. Evaluation of the New Malaria Diagnostic Device in THAI (FCM study)	2019年11月 (FPI) ~2022年8月 (LPO予定)		
4. Evaluation of the New Malaria Diagnostic Device in THAI for Asymptomatic case (LAMP Study)	2020年2月 (FPI) ~2022年8月 (LPO予定)	1,537/3,300	
5. Evaluation of the New Malaria Diagnostic Device in THAI for Asymptomatic case (FCM study)	2020年2月 (FPI) ~2022年8月 (LPO予定)		
6. Clinical Detection Performance & Usefulness of Novel Coronavirus RDT kit in the PHL 1	2022年1月 (FPI予定) ~2022年4月 (LPO予定)	/150	
7. Clinical Detection Performance & Usefulness of Novel Coronavirus RDT kit in the PHL 2	2022年1月 (FPI予定) ~2022年4月 (LPO予定)	/150	
8. Clinical Detection Performance & Usefulness of Novel Coronavirus RDT kit in the PHL 3	2022年1月 (FPI予定) ~2022年4月 (LPO予定)	/150	
9. Clinical Detection Performance & Usefulness of Novel Coronavirus RDT kit VNM	2021年9月 (FPI) ~2021年12月 (LPO)	200/150	
10. Study of Clinical Performance of COVID-19 LAMP Comparison with RT-PCR in The PHL	2022年1月 (FPI予定) ~2022年4月 (LPO予定)	/100	
11. Study of Clinical Performance of COVID-19 LAMP Comparison with RT-PCR in IDN	2021年8月 (FPI) ~2022年4月 (LPO予定)	96/100	
12. In vitro Antibiotic Susceptibility of Gram-negative Bacteria isolated in VNM 2	Under protocol development	/1,600	
13. A Phase 3 Study of Recombinant Spike Protein for the Prevention of COVID-19 in the PHL & VNM	Under site identification	/54,000	
14. A study of efficacy of Aminolaevulinic acid for Malaria in THA	Under protocol finalization	/74	
15. Neonatal Sepsis –Empiric treatment strategic public health trial in VNM	Under protocol finalization	/3000	
16. Study of Virtual Reality Therapy for Depression in THA	Under protocol finalization	/100以下	
17. A Phase 3 Study of Efficacy and Safety of the Drug for Mild COVID-19	Under site identification	/1,000	
18. Study of New Antibiotics for AMR in ASEAN	Consulting now		
19. Study on Prediction of COVID-19 Severity by Inflammatory Cytokines	Under budget negotiation & under protocol development		
20. International Development of RDT Kits for Influenza and SARS-CoV-2 Antigens in ASEAN	Consulting now		
21. New Bio Marker “Laminin γ2 Single Chain” R&D for Hepatocellular Carcinoma	Under budget negotiation & under protocol development		
22. Ovarian Cancer Marker Development in ASEAN	Consulting now		
23. Umbilical Cord-derived Mesenchymal Stromal Cells Therapy for COVID-19 Related ARDS	Consulting now		
24. Development of HbA1c & Other Testing Device for diabetes Mellitus in ASEAN	Consulting now		

Investigator-Initiated
Clinical Trials

of subject enrolled/Target # of subject

(Actual & Expected) Sources of Operational fees and Research fund

Japanese Public Funds

- ◆ Operating expense subsidy by MHLW
- ◆ AMED (<https://www.amed.go.jp/en/index.html>)
- ◆ ERIA (<https://www.eria.org/>)

International Funds

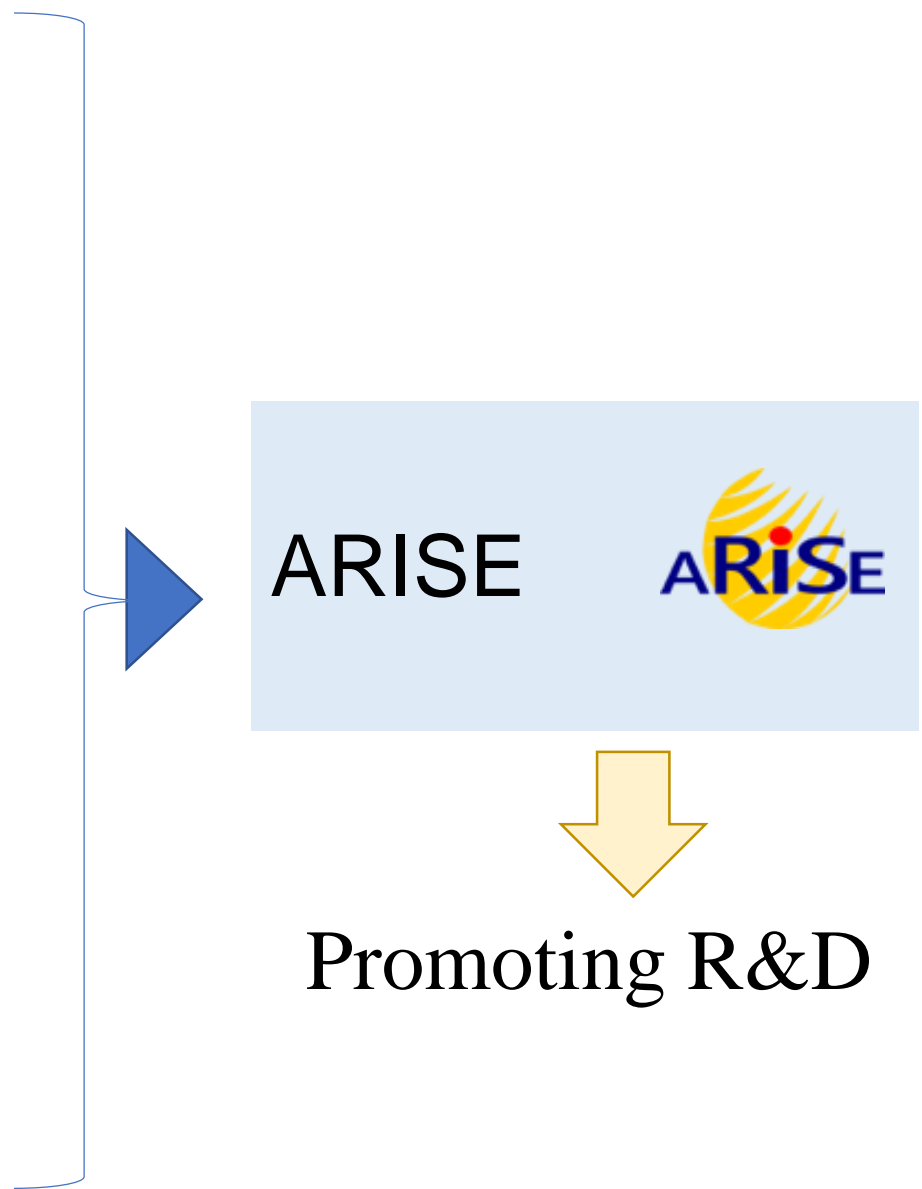
- ◆ ADB
- ◆ Gates Foundation
- ◆ e-Asia fund
- ◆ GHIT

Each country's domestic budget

- ◆ Domestic funds
- ◆ Domestic research grants

Company's R&D budget

- ◆ Medical Device company
- ◆ Pharmaceutical company



ARO Alliance for ASEAN & East Asia (ARISE)

ARISE Chief Representative



ARISE Secretariat



European Clinical Research Infrastructure Network (ECRIN)



Cooperation with global clinical research networks

Cooperation with Japanese organizations



Clinical Research Initiative for Global Health (CRIGH)



ARiSE

Accelerate in Asia

Research collaboration with Asian countries

Establishment of NCGM offices in Asia

- Investigator-Initiated Trials
- Research Strategy
- Capacity Development
- PAPPs
- Regulatory Consultation
- Quality Management
- Health Diplomacy



Indonesia office, University of Indonesia



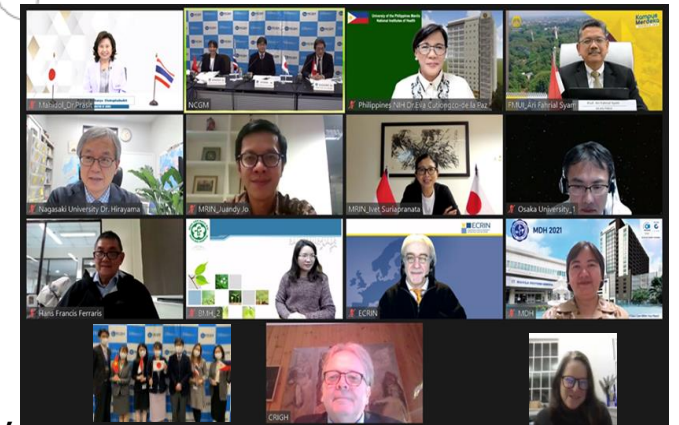
Vietnam office, Bach Mai Hospital



Philippine office, University of Philippines Manila

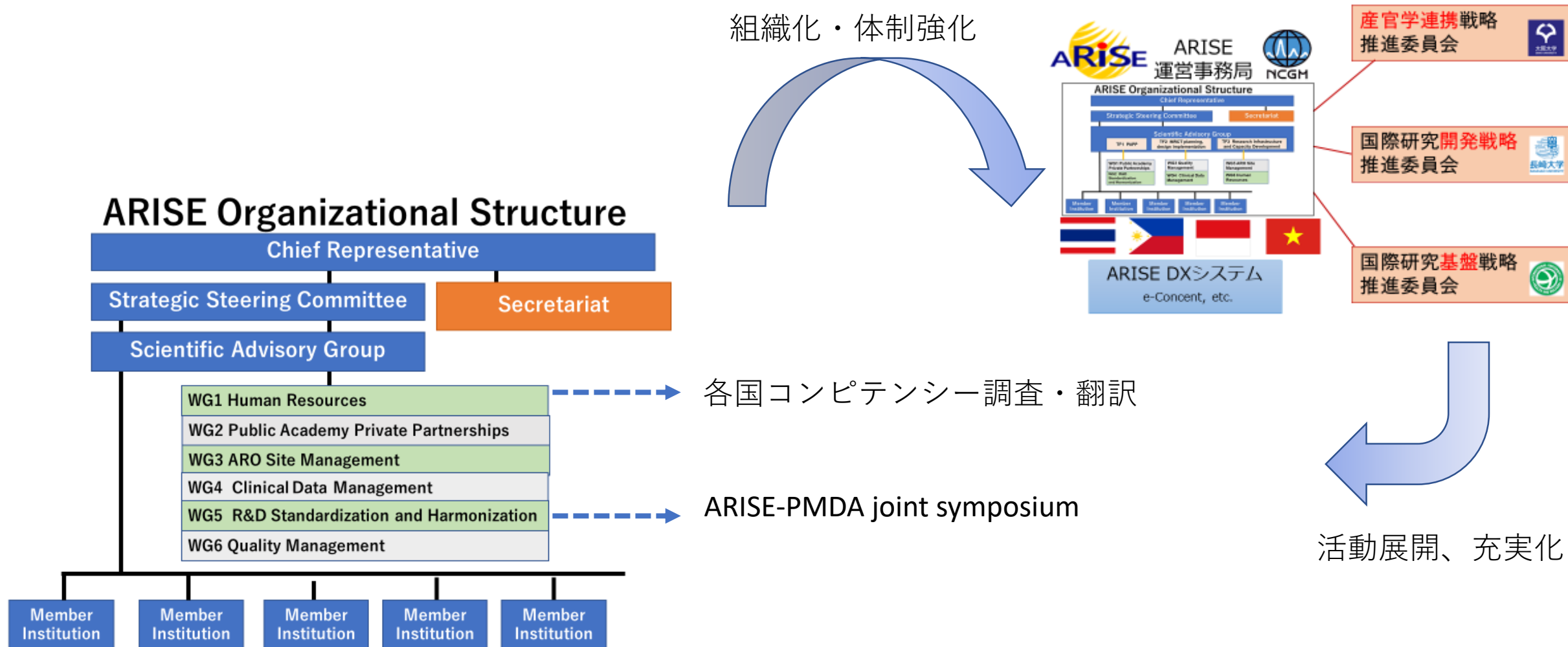


Thai office, Faculty of Medicine Siriraj Hospital, Mahidol University





ARISE Members

各戦略委員会とWGとの連携に向けて



臨床研究専門職のためのコンピテンシー文書のアジア語翻訳と ARISE加盟国におけるコンピテンシー調査研究

- Harvard MRCTCenterとCRIGHと活動・研究協力
- コンピテンシー調査：4月末現在、ARISE 5か国より993回答（オンライン回答完遂率約79%）
- 成果物（令和4年度中）：調査結果論文発表、コンピテンシー現地語訳の各国での論文発表

	Competency assessment survey	Language of Competency Translation	Cooperative organization
ARISE/ NCGM 2021～2022年12月 	Thai	Thai	Mahidol University, Faculty of Medicine Siriraj Hospital
	Indonesia	Indonesia	The University of Indonesia, Department of Pharmacology and Therapeutic Pre-Clinic
	Vietnam	Vietnamese	Bach Mai Hospital
	The Philippines	(English)	The University of Philippine Manila, National Institute of Health
	DRC	(French)	The University of Kinshasa, faculties of Medicines and Pharmaceutical Science
CRIGH Project 2 (2016～)  <ul style="list-style-type: none"> • Leader: Mr. Allan Wirsdorf of F-CRIN • Supported by Harvard MRCT Center • Global Survey was done by Harvard MRCT Center (2016、2020) 	Japanese		NCGM , Osaka University, NCC
	French		draft translation by F-CRIN (France) – Proofread by KCE (Belgium), LIH (Luxembourg), SCTO (Switzerland) and IRESSEF (Senegal) - Contacts currently being identified for proofreading by Morocco and Canada
	Portuguese		draft translation by PtCRIN (Portugal) – Proofread by Fiocruz (Brasil) – To be proofread by CISM (Mozambique) and Angolan contact currently being identified
	Italian		draft translation by Mario Negri and ISS (Italy) – Proofread by IFO - Regina Elena and San Gallicano Research Institutes (Italy) – To be proofread by SCTO (Switzerland – Lugano CTU)
	Spanish		translation by APEIC (Mexico) of v3.0 already available (APEIC contacted for complementary v3.1 translation) – To be proofread by Spanish professionals
	German		translation team currently being set up (Austria, Germany, Luxembourg and Switzerland (the last two having agreed to participate))
	Russian		draft translation by ACTO (Russia) / Proofreading ongoing
	Korean		contacts currently being identified (KoNECT)



JTF Core Competency Framework for Clinical Research Professionals



> Ther Innov Regul Sci. 2022 Mar 31. doi: 10.1007/s43441-022-00395-z. Online ahead of print.

Self-assessed Competencies of Clinical Research Professionals and Recommendations for Further Education and Training

Stephen A Sonstein ¹, Elias Samuels ², Carmen Aldinger ¹, Sarah A White ¹, Barbara E Brier ^{3, 4}

Affiliations + expand

PMID: 35357687 DOI: 10.1007/s43441-022-00395-z