

Prospects for ARO's Clinical Study Support Platform and NCGM International Infectious Diseases Forum

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Thank you for the time here today. I would like to talk about the "Prospects for ARO's Clinical Study Support Platform and NCGM International Infectious Diseases Forum.

International ARO activity –How can we create value and service?

ARO : Organizations that support clinical and non-clinical research, including drug development by utilizing the functions of universities which have research institutes and medical institutions.

Reference : AMED Homepage : <https://www.amed.go.jp/program/list/05/01/011.html>

Comparison of R&D Support Activities

Objectives: R&D	CRO	ARO	
		General ARO	Intn'l ARO NCGM, CCS, DIT
Optimize medical care (Regulatory approval, guidelines, for drugs not approved in the respective country concerned)	Based on corporate marketing strategies led by company	Focus PI's Clinical questions and research question	Investigator initiated +PAPP, Focus public interest then boosting industry
R & D of new pharmaceutical and IVD products	Focus on corporate product development projects	Investigator initiated clinical study/trial	Investigator initiated clinical study/trial
Cutting edge R&D	Out-licensed products from academia	Up to licensing out to industry	Researchers + industry, potential markets/Grants
Urgent situation	Depends on market attractivity, corporate strategy include CSR	Academic support	Engage based on policies

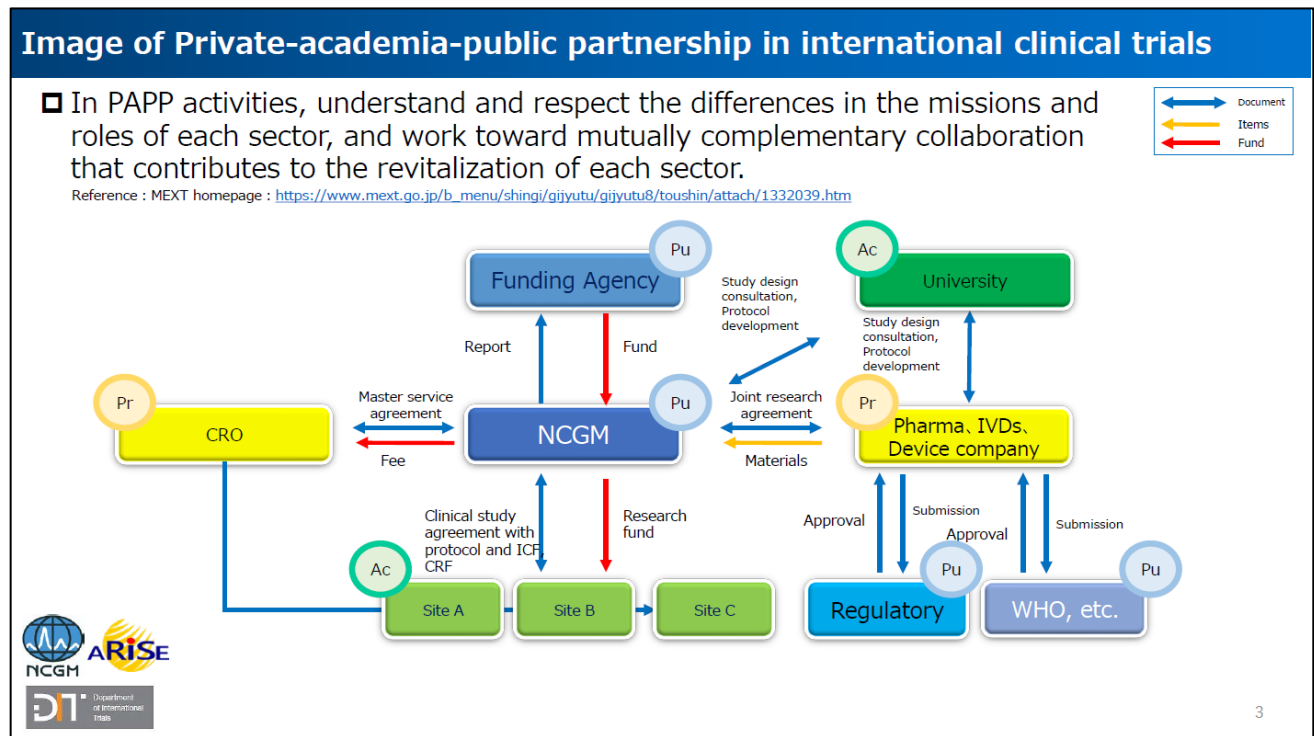


AROs often support public benefit activities and are expected to contribute in the above cases

First of all, let me introduce to you the International ARO. This forum uses the AMED financial support. Here you can see the definition of ARO by AMED. "The organizations that support clinical and non-clinical researches, including drug development, by utilizing universities that have research institute facilities and medical institution affiliations." With this definition, I would like to talk about ARO today. And here, you can find the comparison of the supportive activities. There

are four major objectives by ARO. First and foremost is the optimization of medical care. As an international ARO, we try to establish the investigator initiated clinical trials to support the research as a whole. The second one is to promote the R&D of new pharmaceutical and IVD products that is also investigator initiated-based study. And the third one is the cutting-edge R&D. Here, the researchers and the industry work together to identify the research potentials and to gain grants.

Lastly, the International Global ARO does activities in urgent situations based upon the policy for public health contribution.



This slide shows the image of Private-Academia-Public partnership in international clinical studies and trials. Green indicates academia, Japanese universities and clinical trial sites. And blue indicates the public. Yellow represents industry. So, in this collaborative manner, the Public-Academia-Private partnership is taking place to promote international clinical trials; and, this is where we are supporting exactly. For this kind of partnership, each sector's mission, as well as roles, have to be well understood by each other, so that each can complement with a collaborative mind for the enhancement of shared activities.

Prospects for the NCGM International Forum on Infectious Diseases

Principles

- ❑ Building an international ARO network (ARISE) and supporting clinical studies/trials
MOUs:7, collaborative offices:3, CSAs:8, studies under subject enrollment:6,
developing protocols:3
- ❑ Training of future clinical research professionals
- ❑ **NCGM international infectious diseases forum**
Bridge among Private-academia-public

Three hurdles to promote the globalization of medical products

- ❑ Hurdle 1 : Planning and conducting international clinical trials.
Expectation : How quickly can study sites be identified?
How quickly can case enrollment proceed?
- ❑ Hurdle 2 : Filing regulatory applications in the countries concerned.
Expectation : Can we get approval with fewer steps?
- ❑ Hurdle 3 : Dissemination.
Expectation : Information that contribute to the public interest; corporate and business strategies cannot be drawn only within the framework of CSR. How to break through?

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The following are the prospects for the NCGM International Infectious Diseases Forum based on such partnership. Basically, we would like to do these three things. First one is the creation of an international ARO network aimed at supporting clinical studies. The second one is the training of future clinical research professionals. And the third one is this forum. We would like to position our center as the link among partners. With regards to the development or promotion of the globalization of medical products, there are many hurdles that we face; for example, in the planning and conducting of international clinical trials, it has been expected from us to quickly identify study sites and promptly enroll and follow-up the subjects through submission. We need to think about efficiently shortening the process and disseminate information that could capture public interest. CSR framework and strategies alone cannot rouse and engage the attention of corporate and business institutions in many cases. So, how can ARISE break through, to be able to accomplish its objectives?

Amidst the challenges, there are specific cases and information that need to be gathered. And I think this forum can address that. After this session, medical products will be introduced. This is the very first time for us to do so. This is not a promotion activity. Rather, I would like you to think about the medical perspectives and the public interest perspectives as well. I sincerely hope that this activity is going to be one good venue for the Japanese stakeholders to be able to introduce their products to everyone. We aim to facilitate the opportunity for relevant organizations to interact and discuss common interests in clinical and non-clinical products. To doctors and researchers participating from outside of Japan, I believe you have some unique and interesting clinical experience, or sufficient cases for clinical trials and clinical research, or you might be looking for products that's exactly what we would like to introduce and share with you in this forum.

For these purposes, ARISE network was established. We sincerely hope that this forum is going to serve the best interest of everyone.

We look forward to working with you ↓

<https://ccs.ncgm.go.jp/050/en/aboutus/consaltation.html>



This activity is supported by the AMED-supported project "Research Project for Promoting Clinical Studies and Trials (Project for Establishment of Clinical Studies and Trials Network in Asian region)".

Thank you very much for your attention. We would like to also thank AMED for enabling this opportunity. We would like to express our appreciation to everyone.