

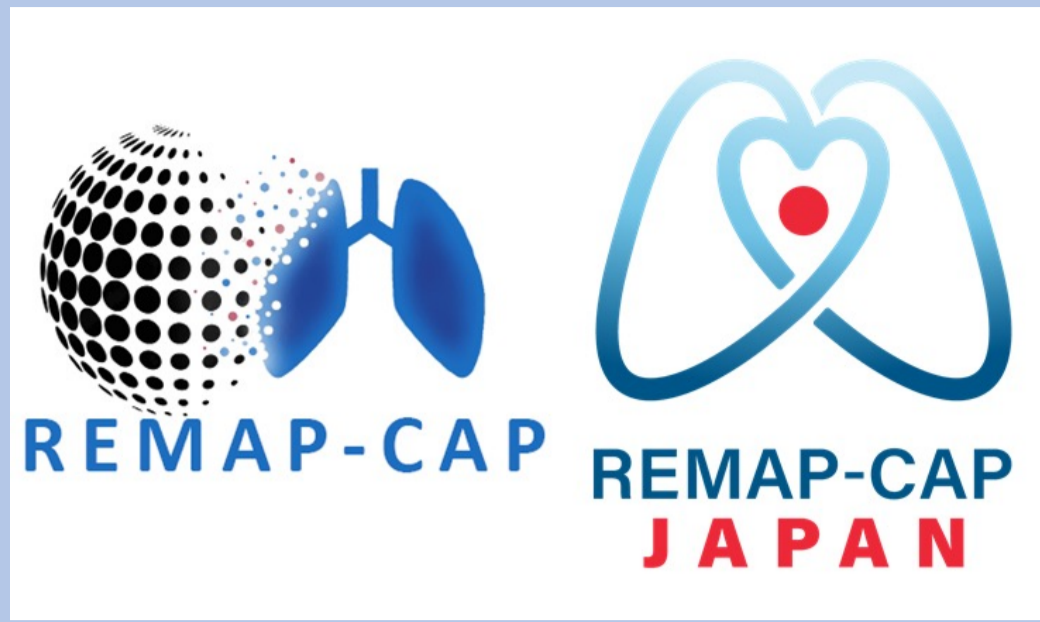
# Enablers and barriers for participating in a pragmatic clinical trial: a questionnaire and interview survey in Japan

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## Introduction

REMAP-CAP: A Randomised, Embedded, Multi-factorial, Adaptive Platform trial for Community-Acquired Pneumonia

REMAP-CAP enables the assessment of multiple therapeutic strategies simultaneously across domains of community-acquired pneumonia.

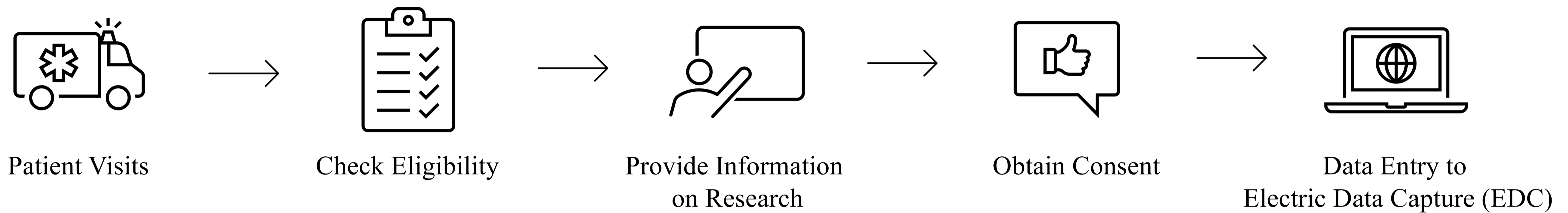
A total of 325 sites across 25 countries have participated in the trial, including 30 sites in Japan.

REMAP-CAP contributes to evidence on multiple therapeutic options such as anticoagulation therapy, tocilizumab, and sarilumab against COVID-19.<sup>1)2)3)</sup>

Thailand is currently preparing to participate in REMAP-CAP, supported by a team from Japan and Singapore.

Four domains (Antibiotic domain, Macrolide duration domain, Mechanical ventilation domain, and anticoagulation for COVID-19 domain) are currently in place in Japan.

## Flow of case registration



## Problems in Japan

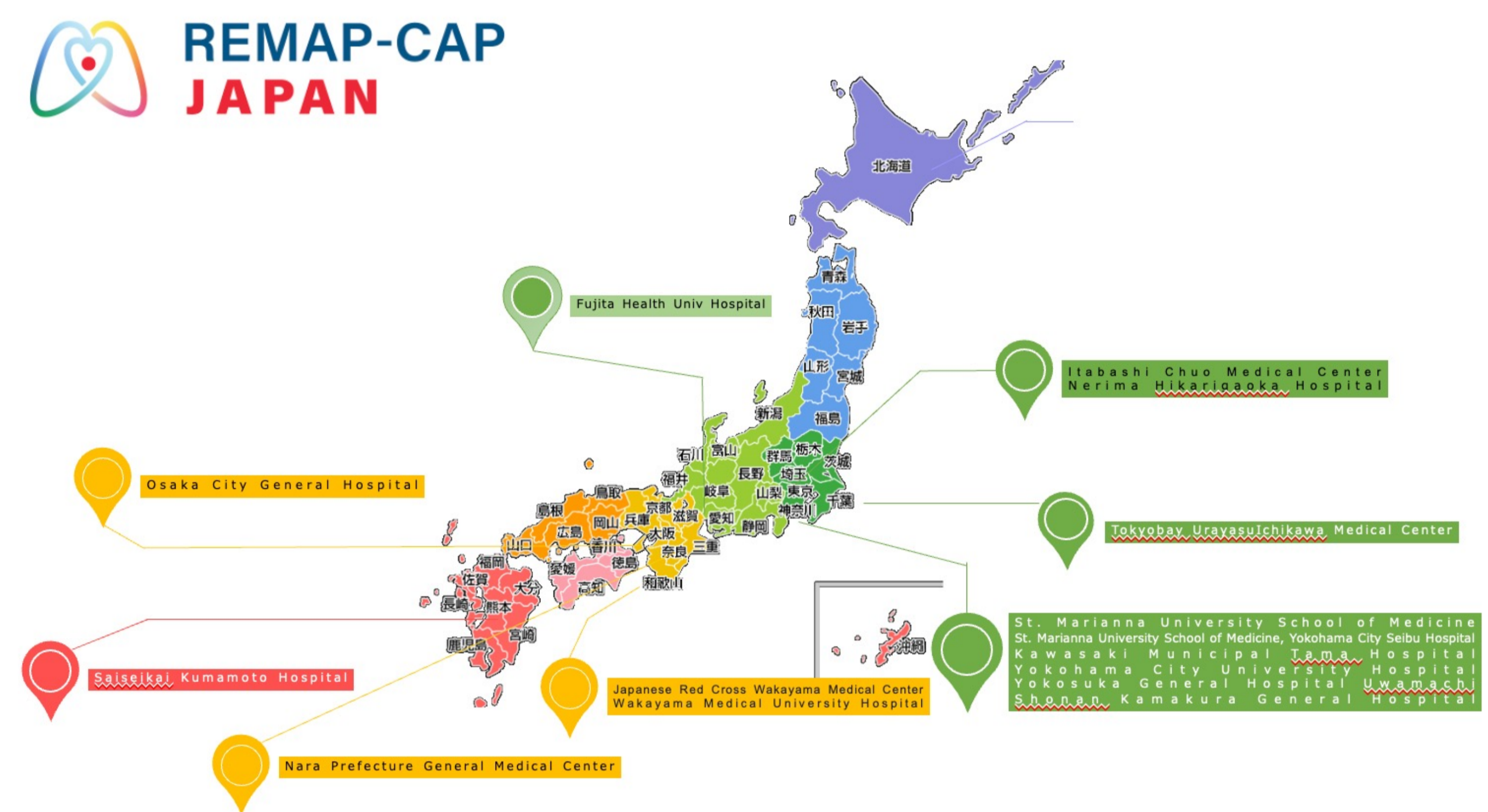
In Japan, 15 facilities are currently participating in REMAP-CAP.

However, 60% of these facilities have never enrolled patients, and even those who have enrolled are not constantly enrolling patients.

## Aim

We aim to identify opportunities and barriers to further improve and sustain site engagement for the research in Japan.

Sharing the experiences in Japan would be helpful for further research collaboration between Thailand and Japan.



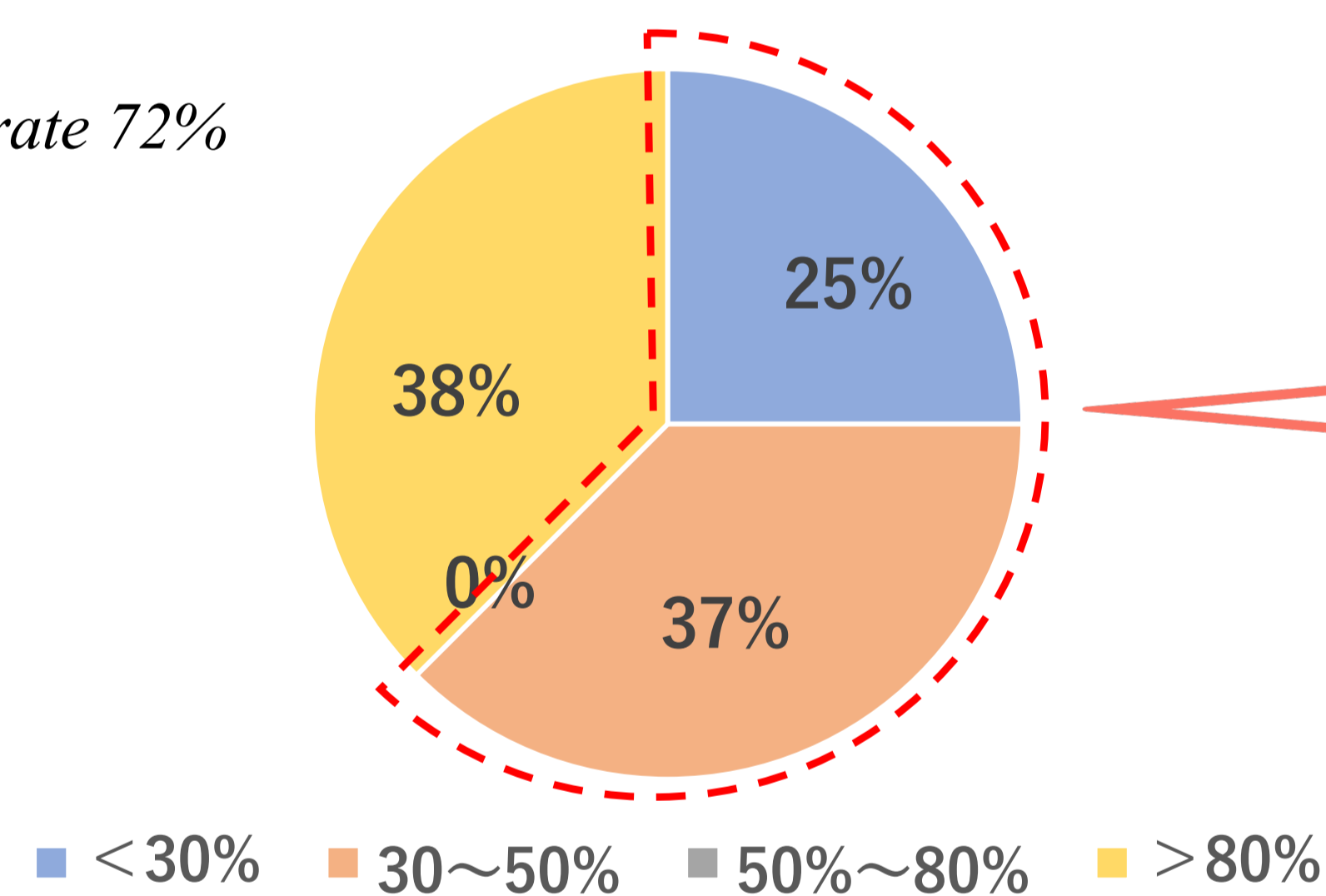
## Material & methods

Online questionnaires and interviews were conducted among REMAP-CAP investigators at participating sites.

## Result

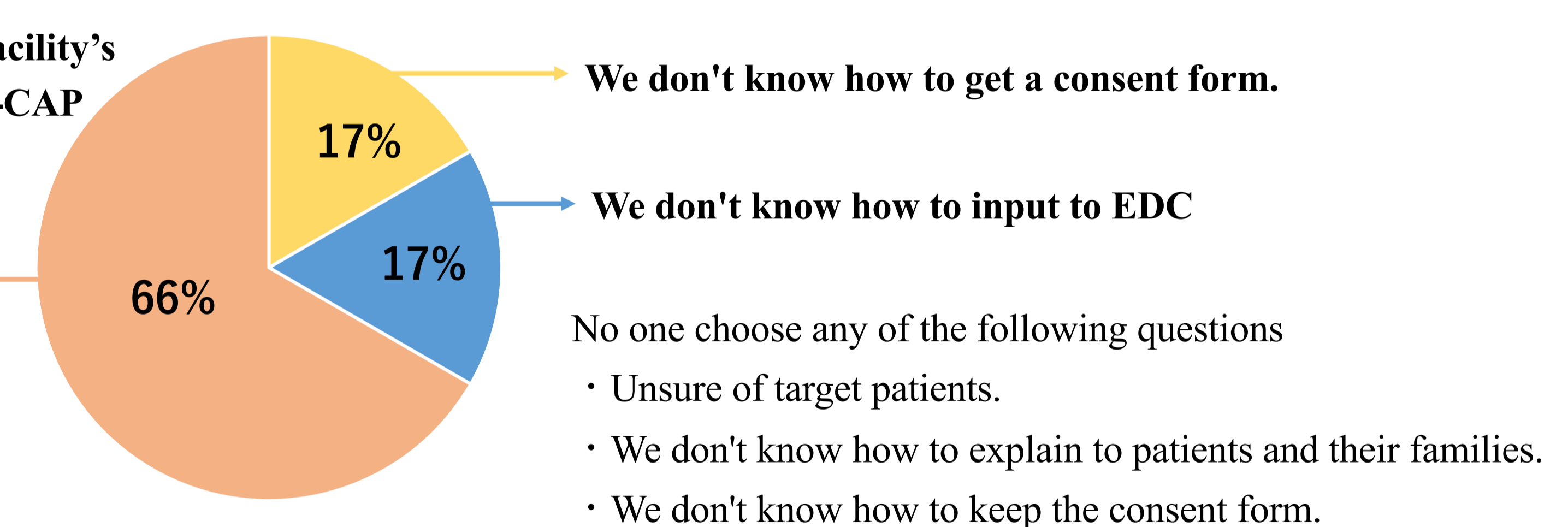
**What % of your colleagues in your department do you think understand REMAP-CAP eligibility, explain the study to patients, obtain consent and enter the data into EDC?**

Response rate 72%



**More than half of respondents answered that less than half of their colleagues understand the research processes.**

**Among those who selected "less than 50%." In what aspects do you think they have little understanding?**



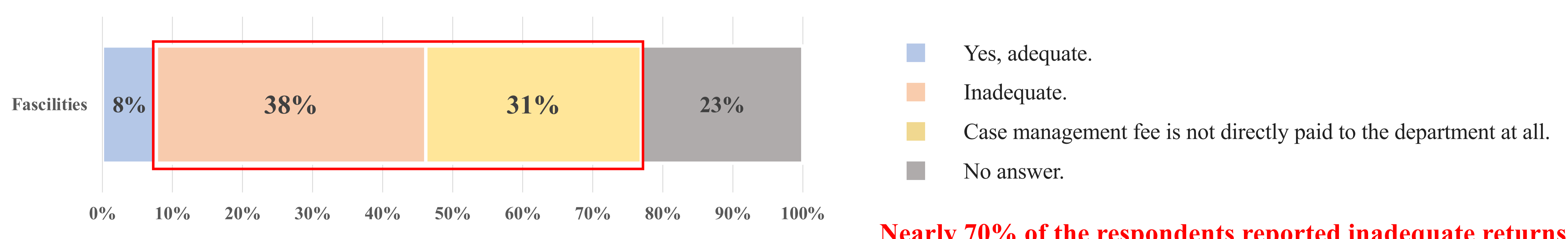
**More than 60% of respondents indicated a lack of awareness of participation in REMAP-CAP**

**What efforts do you think should be made to improve enrollment in REMAP-CAP? (Free answer)**

- I would like some kind of incentive for participating in this study, such as conference presentations, authorship etc.
- As it is difficult to enroll the first patient, I need more support to enroll the first case.
- I would like the information sharing on issues of case registration at each facility.

In Japan, the participating sites that enroll patients to REMAP-CAP receive a financial incentive for case management.

**Are the REMAP-CAP case management fees at your institution appropriately utilized for the medical departments and staff who are primarily responsible for case enrollment in this study? (Answers in personal sense)**



**Nearly 70% of the respondents reported inadequate returns.**

## Discussion

REMAP-CAP was able to enroll patients very rapidly during the pandemic. A global network of clinical trials is essential to respond to future outbreaks. We need to collaborate with many institutions to create a large network in preparation for the next pandemic. However, a gap exists between becoming a participating REMAP-CAP site and enrolling cases. In this survey, we investigated different perceptions in REMAP-CAP among physicians. Research is often an additional task for physicians working in Japanese community hospitals, and it was thought to be difficult to align themselves within departments.

## Conclusion

Optimal communication with and support for participating sites were considered important in improving operations of the study.

In addition, it was suggested that in a platform trial, which is perpetual by nature, it is paramount to ensure that the research work is rewarding according to the level of their contribution.

## References

- 1) N Engl J Med 2021; 385: 777 2) N Engl J Med 2021; 385: 790 3) N Engl J Med 2021; 384: 1491