R&D Head Club
Clinical Trial Performance Survey in 2021
Excerpt

April 2022

- This report is an excerpt from a distributed report to a R&D Head Club member company for a research discussion.
- Expenses for this report were borne by member companies of R&D Head Club.
- For the secondary use of this document, see p.41.

Data Center & Working Group Members

The 2021 survey questionnaire was designed, conducted, and analyzed, and this report authored, by a working group made up of representatives from the following 5 companies who were appointed by the R&D Head Club.
In addition, since the questionnaire included questions about the intellectual property of the participating companies, a third-party vendor was assigned, and all study sponsor names and study center names were masked so that the identities of the responding companies would not be known. The masked data were used for data totalization and analysis of the questionnaire.

Performance Working Group members （abc order）

• Astellas Pharma Inc.	Development,	Masaki Kubota
• Eli Lilly Japan K.K.	Clinical Development,	Shino Fujimoto,
• Janssen Pharmaceutical K.K.	Global Clinical Operations Japan,	Dai Kawaratani,
• Pfizer R&D Japan G.K.	Portfolio & Project Management,	Kei Yamashita,
• Shionogi & Co., Ltd.	Clinical Research Department,	Ai Nakamura,

Contents

I. Participating Companies

The survey has been conducted since 2004. The following 20 member companies of the R&D Head Club participated in 2021 survey.

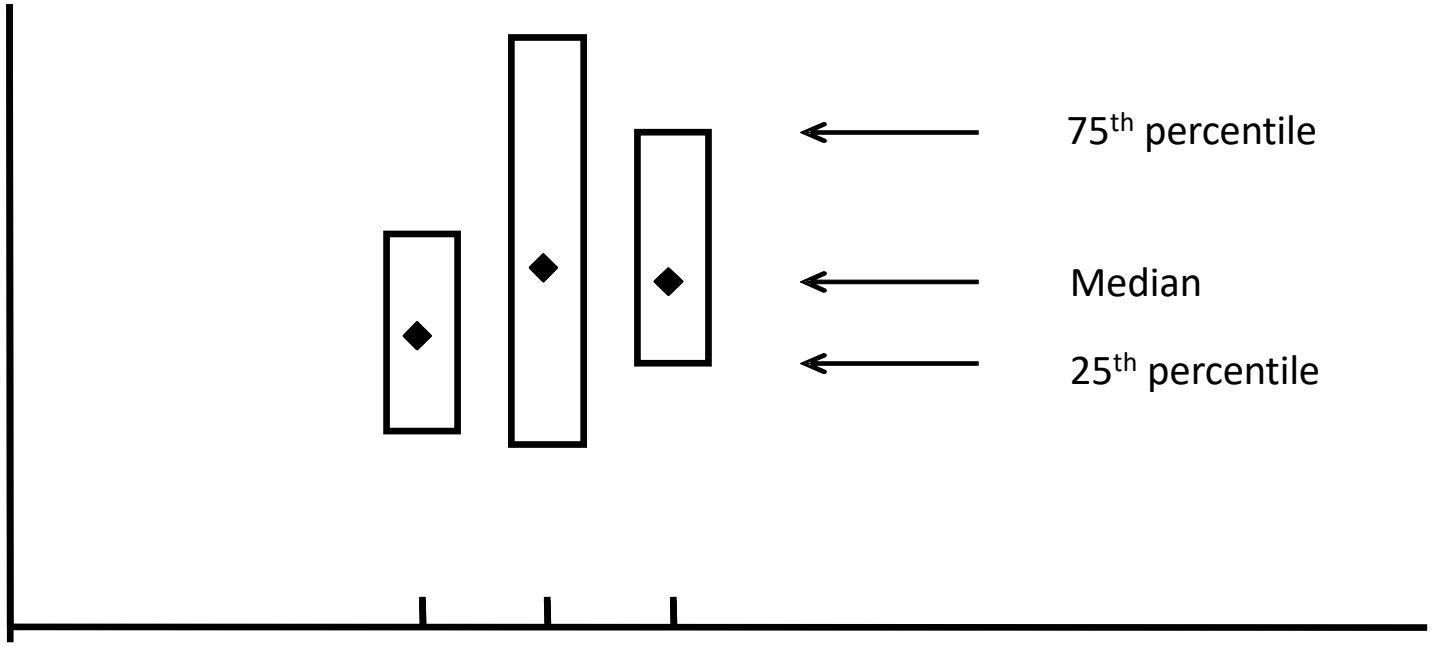
- **AbbVie GK**
- **Amgen K.K.**
- **Astellas Pharma Inc.**
- **AstraZeneca K.K.**
- **Bristol-Myers Squibb K.K.**
- **Chugai Pharmaceutical Co., Ltd.**
- **Daiichi Sankyo Co., Ltd..**
- **Eisai Co., Ltd.**
- **Eli Lilly Japan K.K.**
- **GlaxoSmithKline K.K.**
- **Janssen Pharmaceutical K.K.**
- **Japan Tobacco Inc.**
- **MSD K.K.**
- **Nippon Boehringer Ingelheim Co., Ltd.**
- **Novartis Pharma K.K.**
- **Otsuka Pharmaceutical Co., Ltd.**
- **Pfizer R&D Japan G.K.**
- **Sanofi K.K.**
- **Shionogi & Co., Ltd.**
- **Takeda Pharmaceutical Co., Ltd.**

II. Trials Targeted and Survey Items

- The survey has been conducted since 2004, and data is currently accumulated every 2 years

- Trials targeted by 2021 survey
  - Studies completed between April 1, 2019 and March 31, 2021. (For 2 years)
  - Completed studies were regarded as completed with submission of the final report at the final study site in principle. Therefore, it should be noted that the results of the present data totalization do not include data of studies that required a long period of time to complete the study (studies that have not been completed at the time of the survey in fiscal year 2021).
  - Studies to be included were all clinical trials (including 'Oncology Phase I' and the vaccine study for healthy adults), except for the Phase4 and the healthy volunteer Phase1.
  - Data collected were comparatively investigated by dividing the period based on the starting year of each study into three segments “2011 to 2013,” “2014 to 2016,” and “2017 to 2021.”
  - Data at overseas study sites of the Global study were excluded in principle from the data totalization, except in comparison between the Global study and Japan local study, and the data totalization with the Global study in the background.

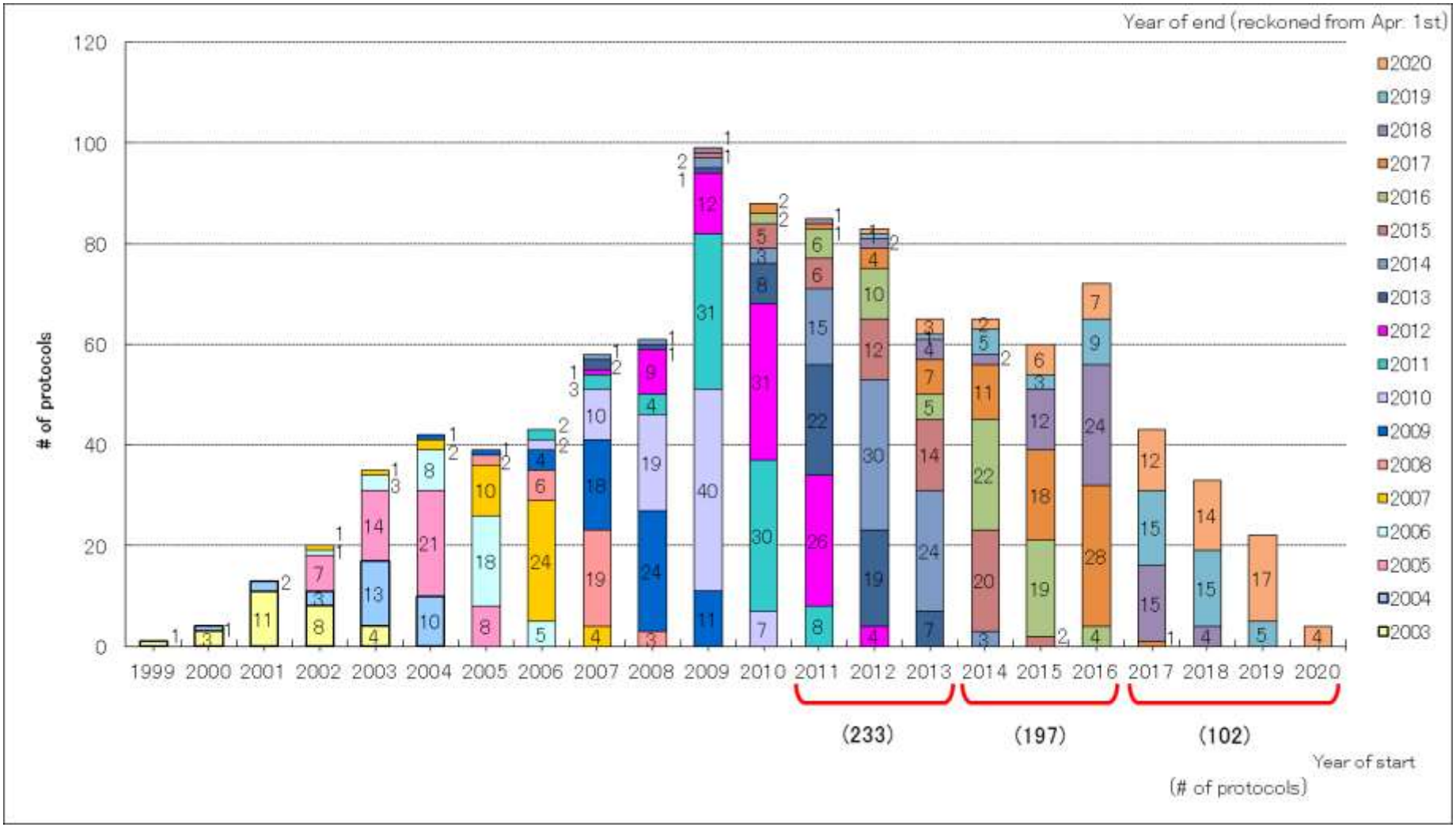
Explanation of a Figure and Box Plot



The lower and upper end of the box in the plot represent respectively 25% point and 75% point of the sample, and the diamond in the center represents 50% point (median).

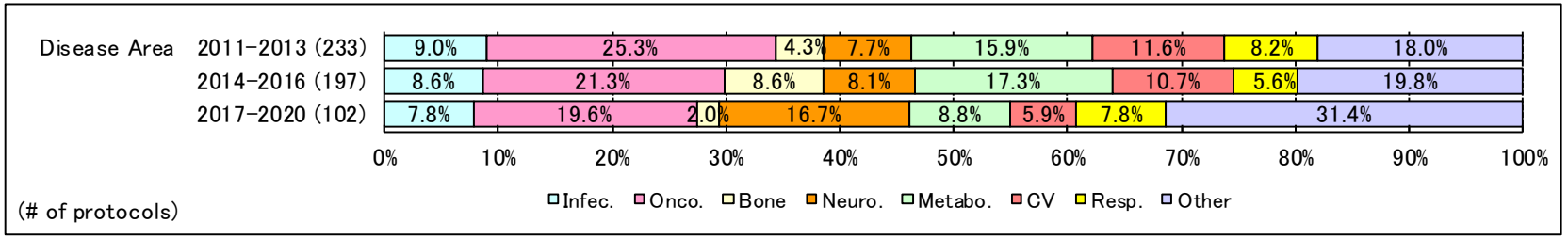
III-1 Background

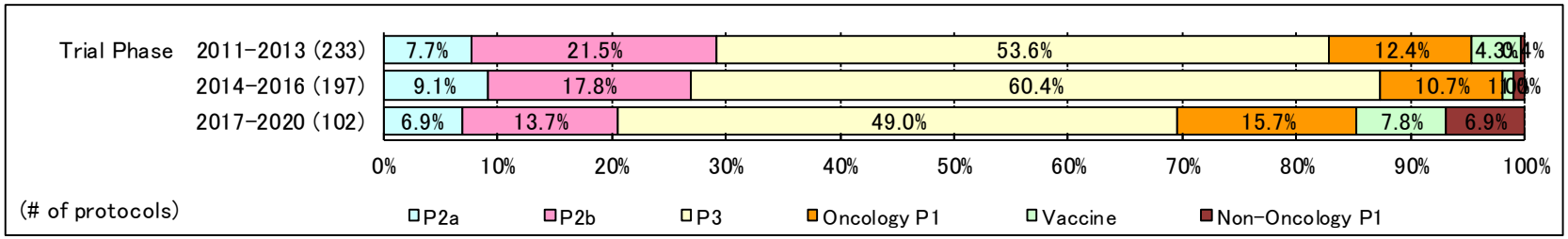
III-1-1 Number of Protocols by Starting Year

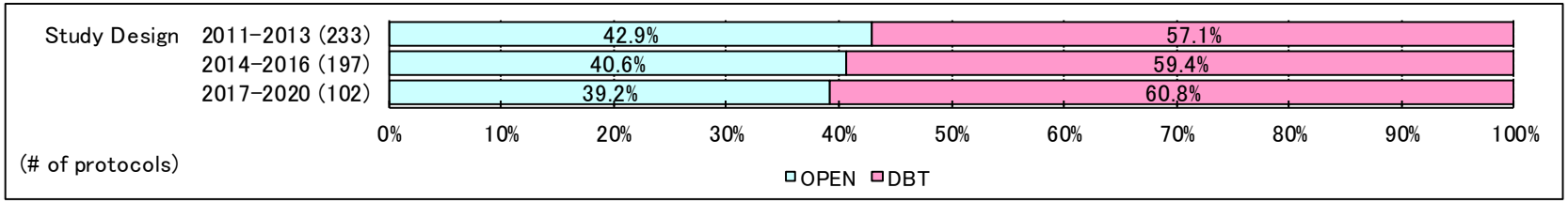


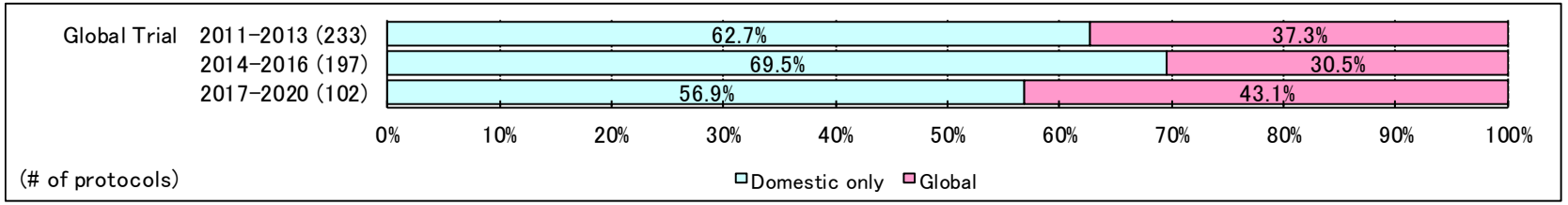
Since this survey is performed on the basis of completed studies, special attention should be paid to non-inclusion of data of studies that takes a long time to complete (i.e., studies not completed at the time of the 2021 survey) particularly in years “2017-2020.”

III-1-5 Background of Protocols 1



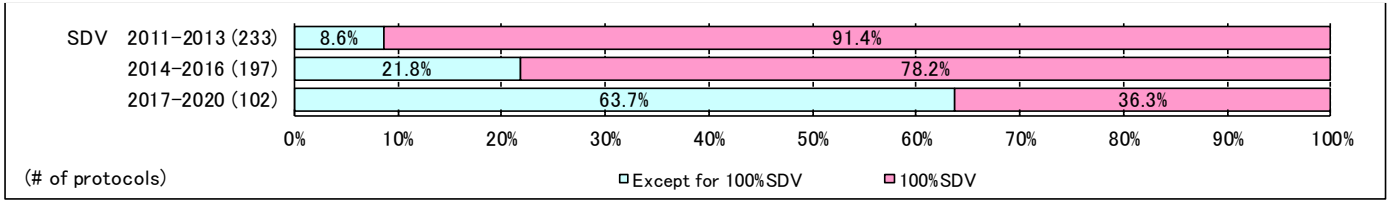


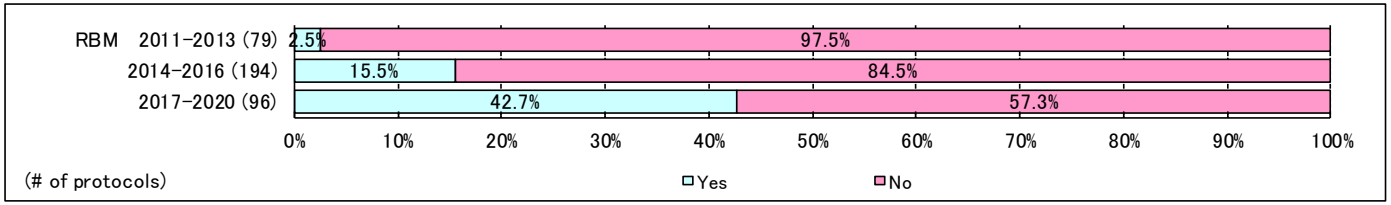




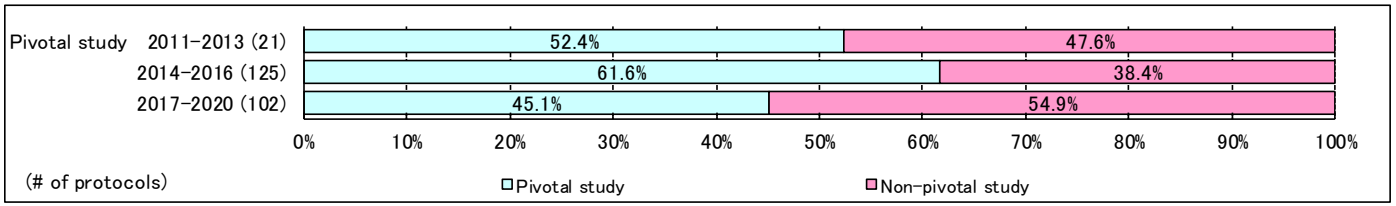
Since this survey is performed on the basis of completed studies, special attention should be paid to non-inclusion of data of studies that takes a long time to complete (i.e., studies not completed at the time of the 2021 survey) particularly in years “2017-2020.”

III-1-5 Background of Protocols 2

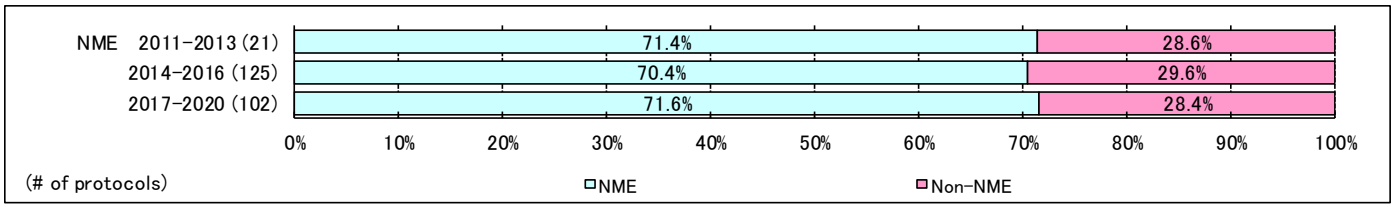




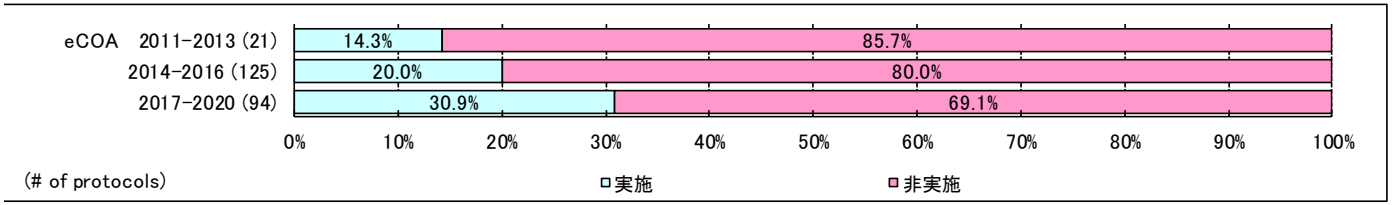
(Survey started in 2017)



(Survey started in 2019)



(Survey started in 2019)



(Survey started in 2019)

Since this survey is performed on the basis of completed studies, special attention should be paid to non-inclusion of data of studies that takes a long time to complete (i.e., studies not completed at the time of the 2021 survey) particularly in years “2017-2020.”

III-1-5 Background of Protocols 3

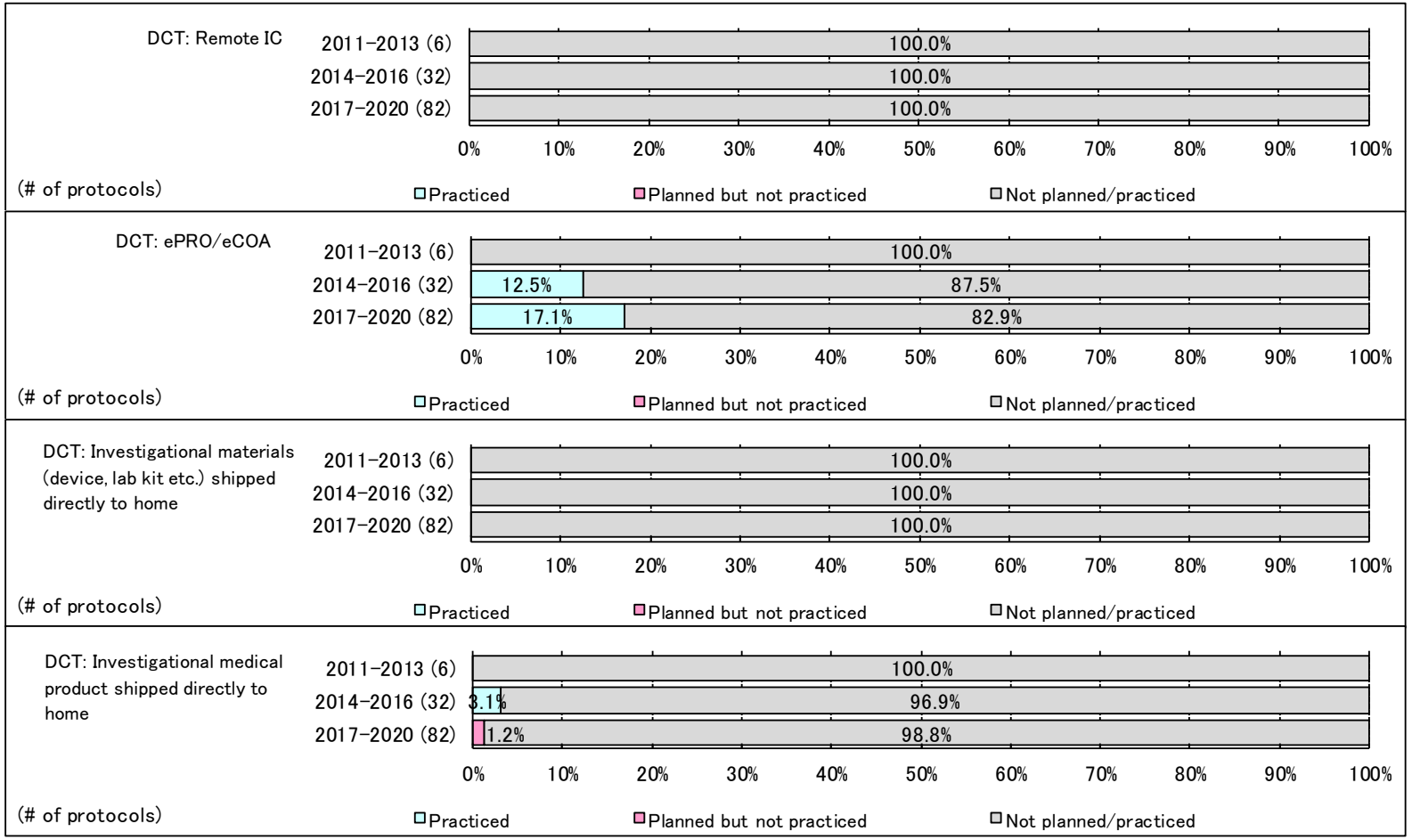
（DCT : Survey started in 2021 ）

[Research Questions]

Practiced: Was planned as a study and practiced in at least 1 subject.

Planned but not practiced: Was planned as a study, but not practiced.

Not planned/practiced: Not planned as a study.



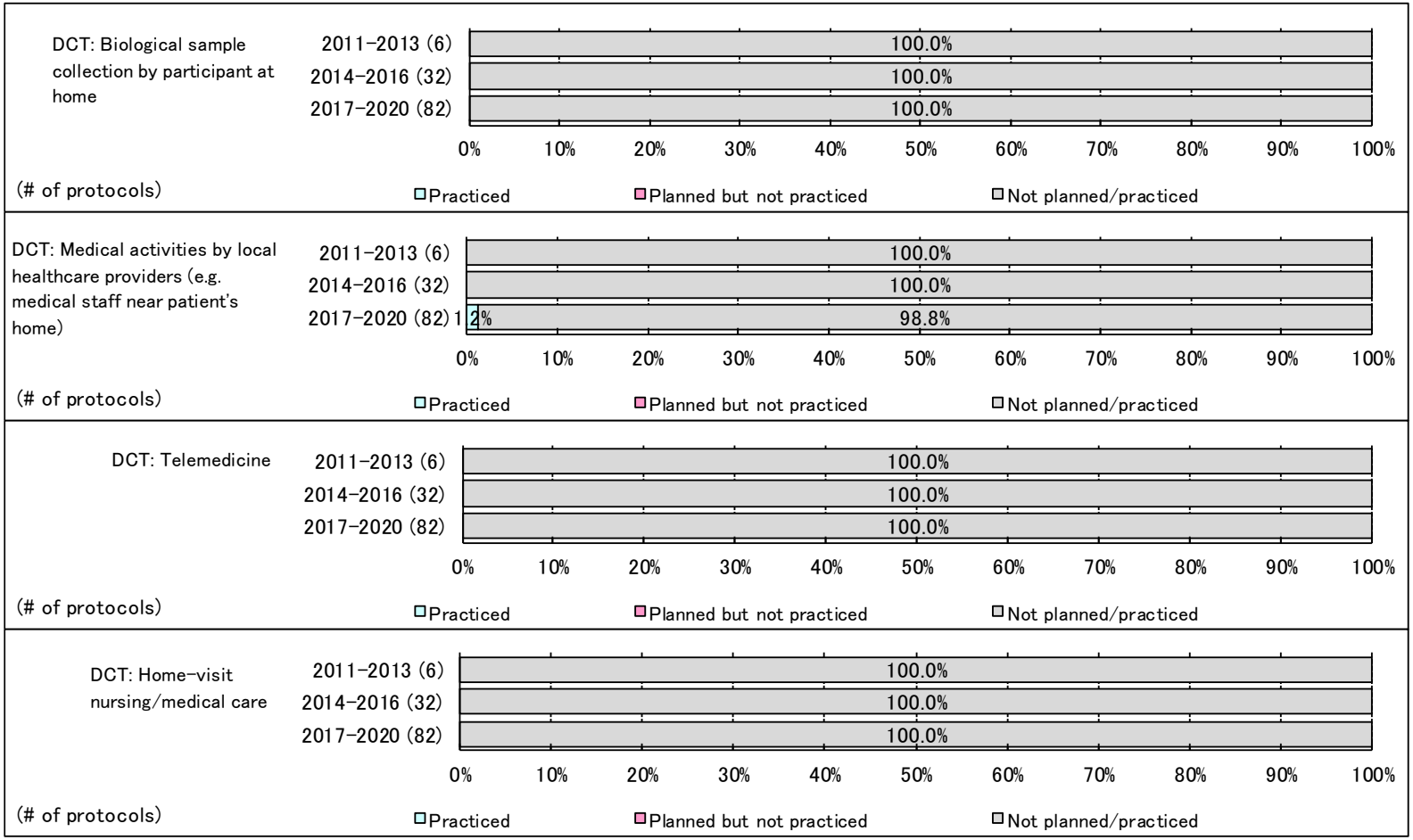
Since this survey is performed on the basis of completed studies, special attention should be paid to non-inclusion of data of studies that takes a long time to complete (i.e., studies not completed at the time of the 2021 survey) particularly in years “2017-2020.”

III-1-5 Background of Protocols 4

（DCT : Survey started in 2021 ）

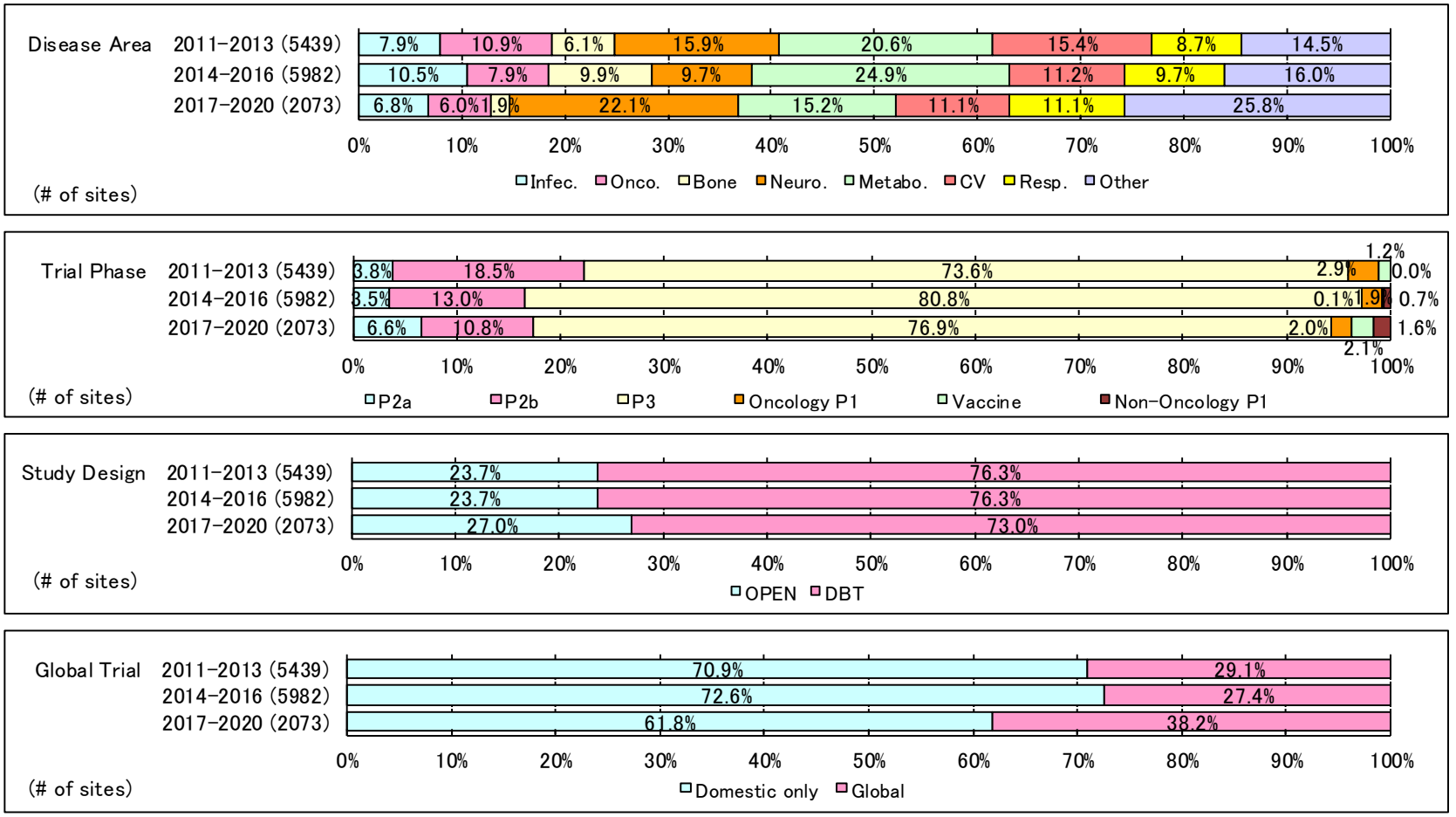
[Research Questions]

Practiced: Was planned as a study and practiced in at least 1 subject.
Planned but not practiced: Was planned as a study, but not practiced.
Not planned/practiced: Not planned as a study.



Since this survey is performed on the basis of completed studies, special attention should be paid to non-inclusion of data of studies that takes a long time to complete (i.e., studies not completed at the time of the 2021 survey) particularly in years “2017-2020.”

III-1-7-1 Background of Sites 1



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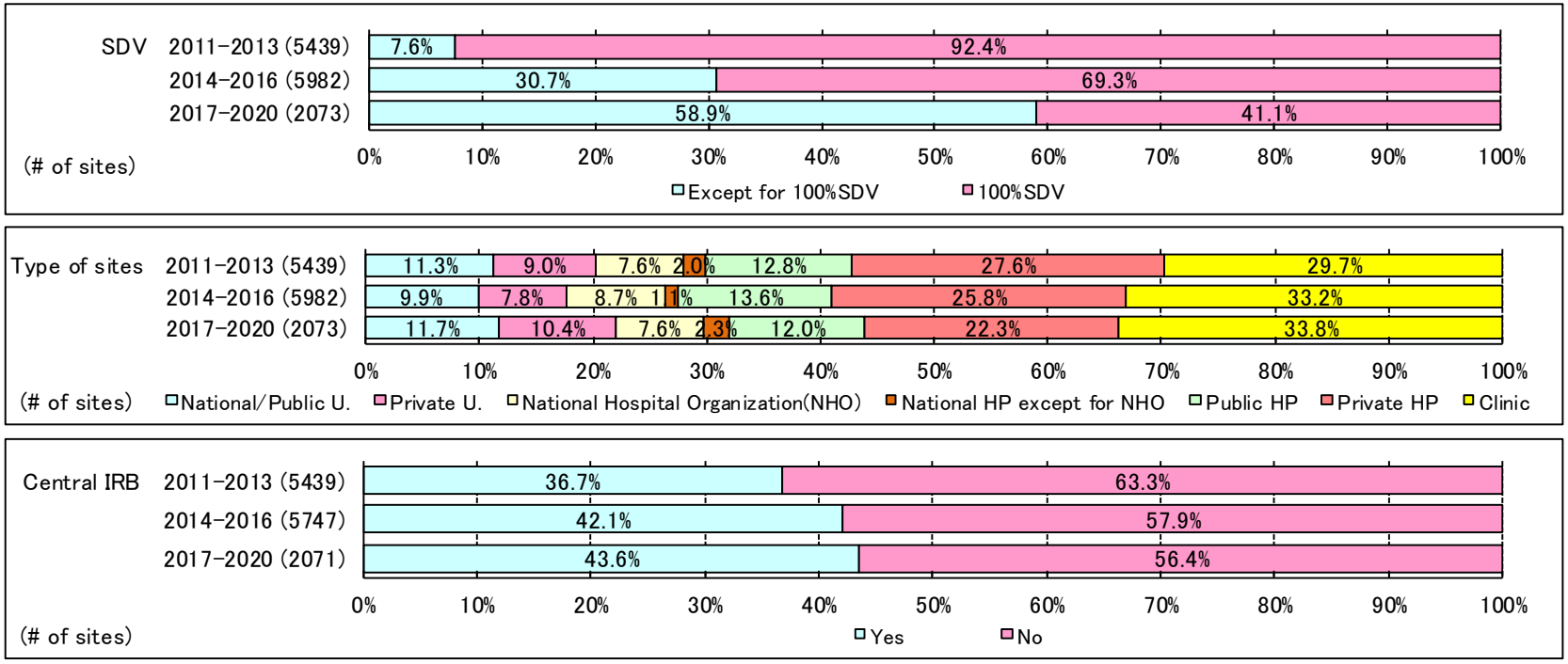
III-1-7-2 Background of Sites 2



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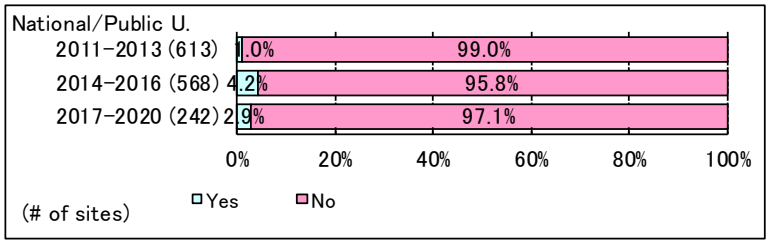
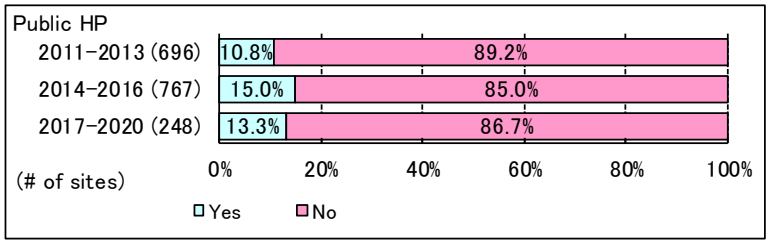
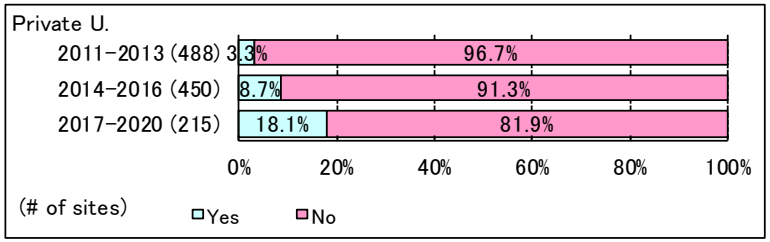
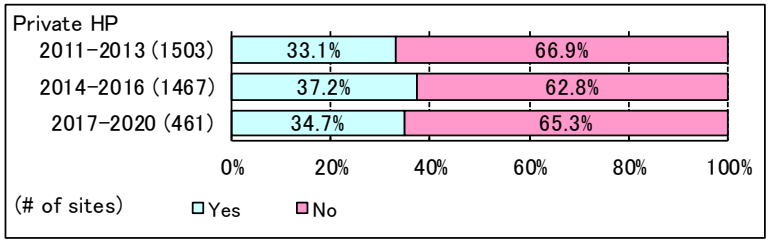
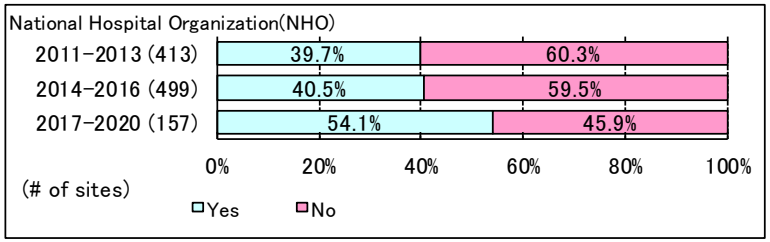
III-1-7-3 Central IRB [Sub analysis]

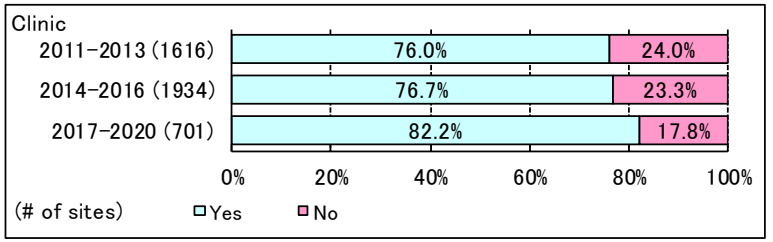


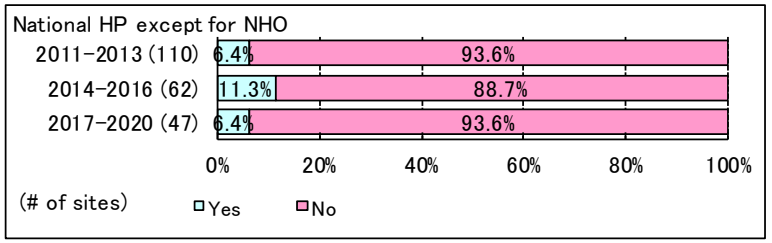








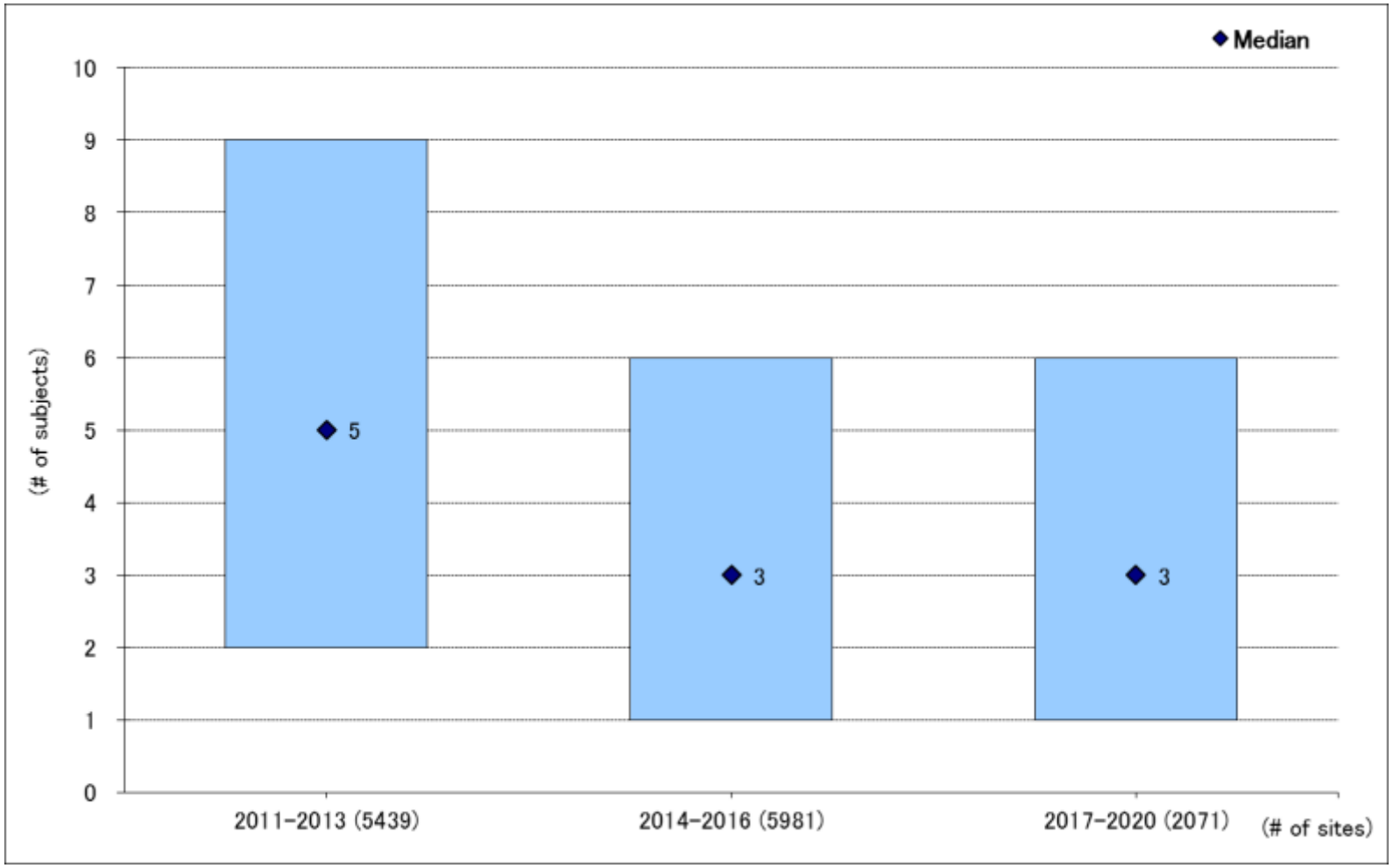




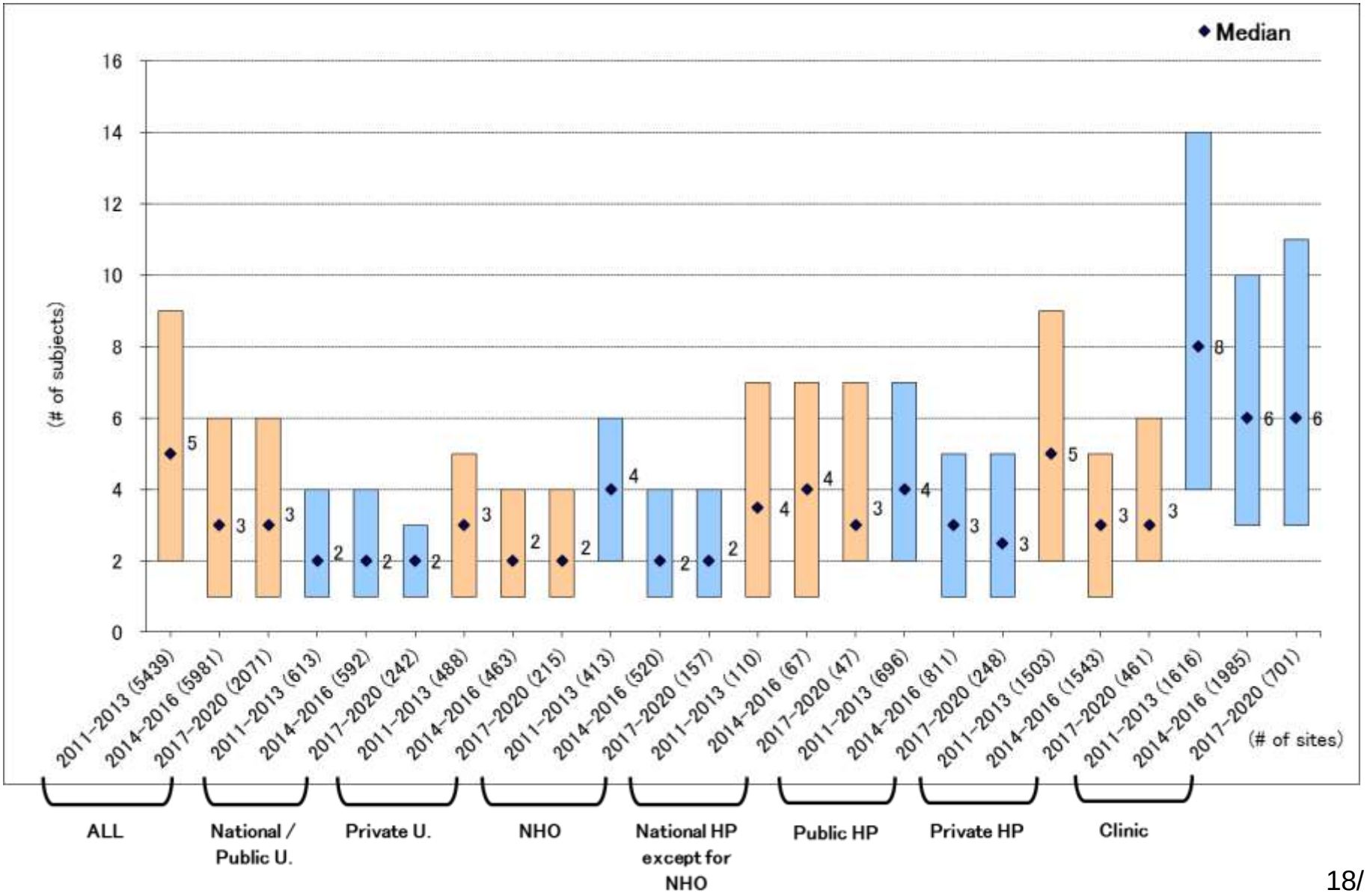
Since this survey is performed on the basis of completed studies, special attention should be paid to non-inclusion of data of studies that takes a long time to complete (i.e., studies not completed at the time of the 2021 survey) particularly in years “2017-2020.”

III-2 Enrollment

III-2-1 Number of Enrolled Subjects per Site

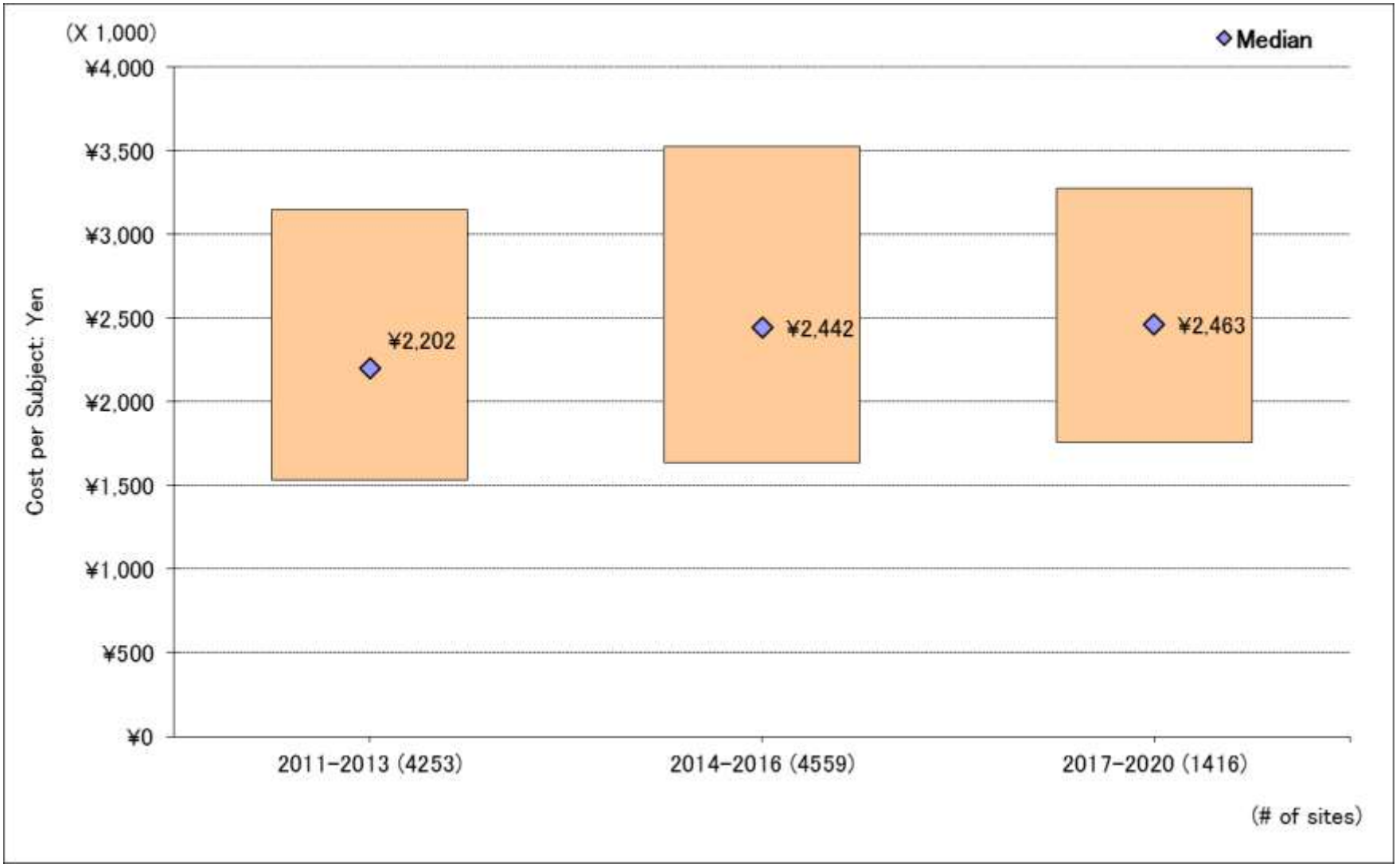


III-2-2 Number of Enrolled Subjects per Site by Type of Site

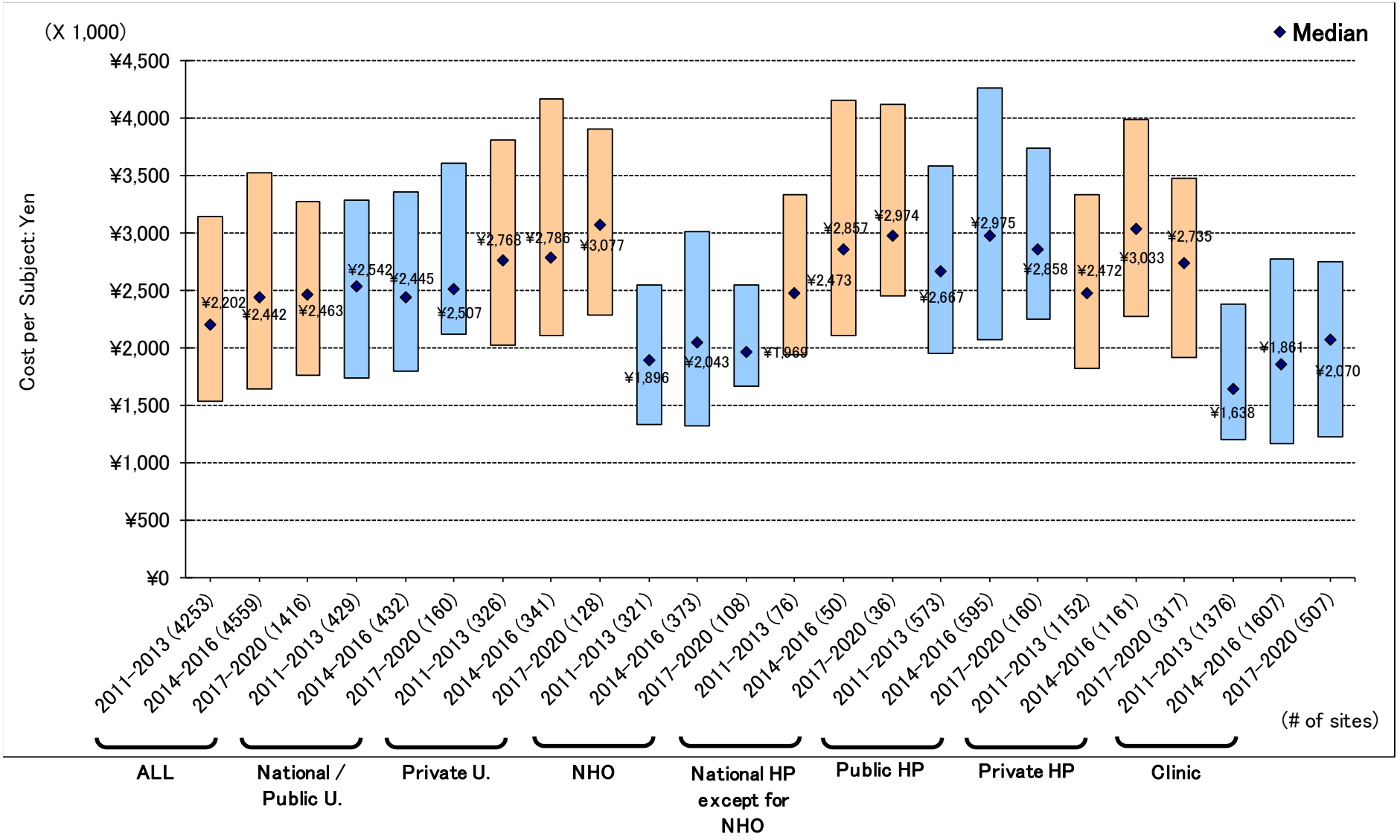


III-3 Cost

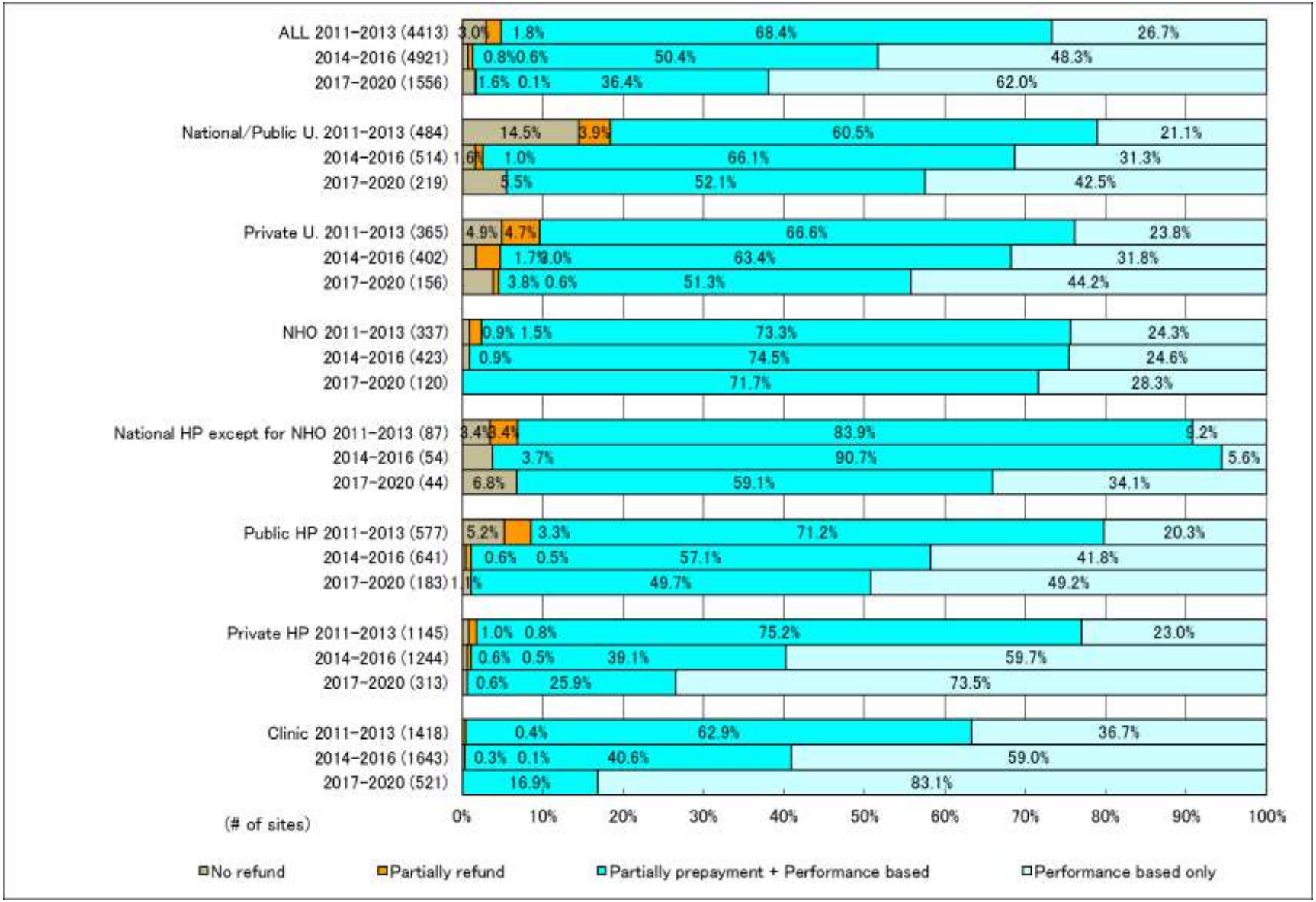
III-3-1 Cost per Enrolled Subject



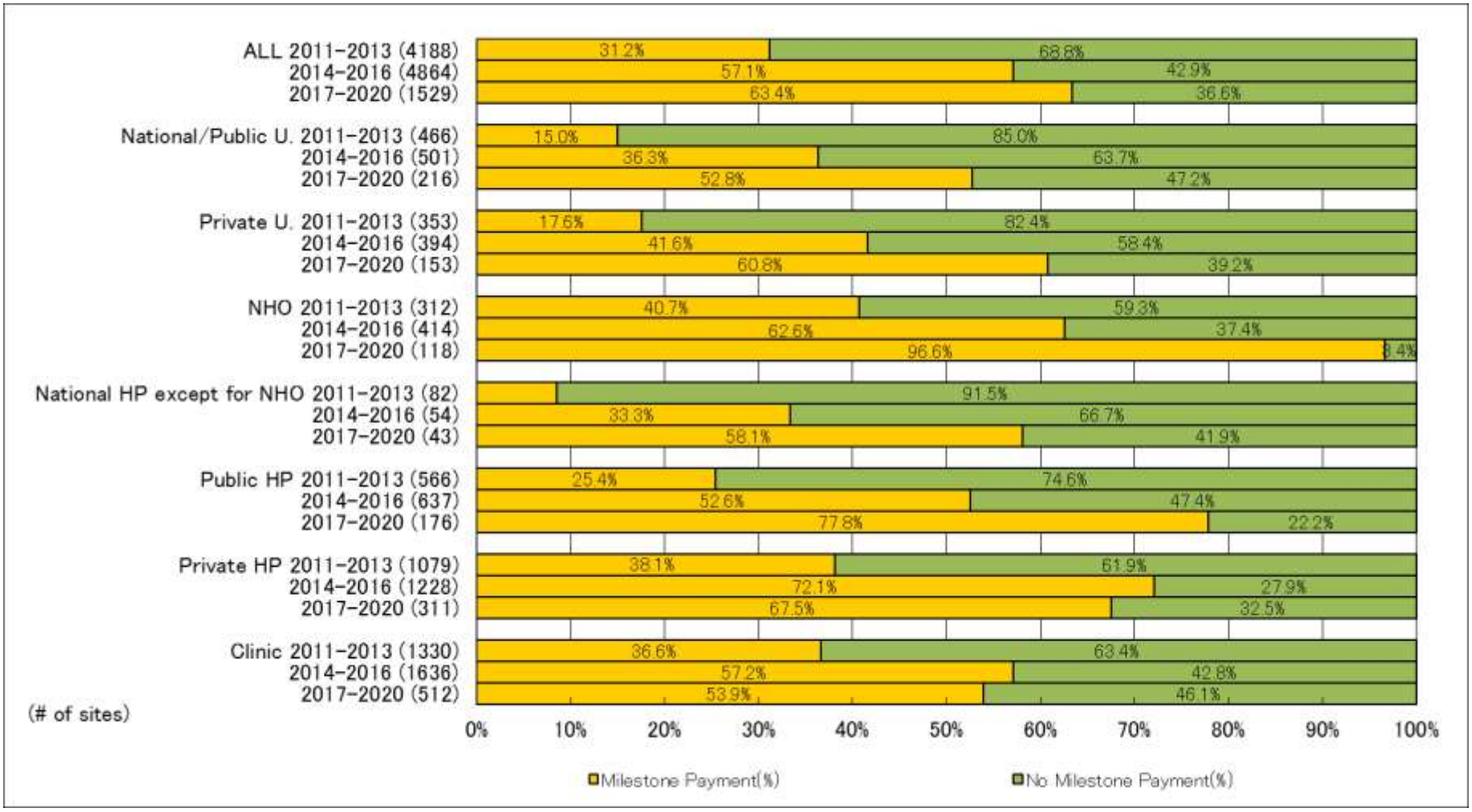
III-3-2 Cost per Enrolled Subject by Type of Site



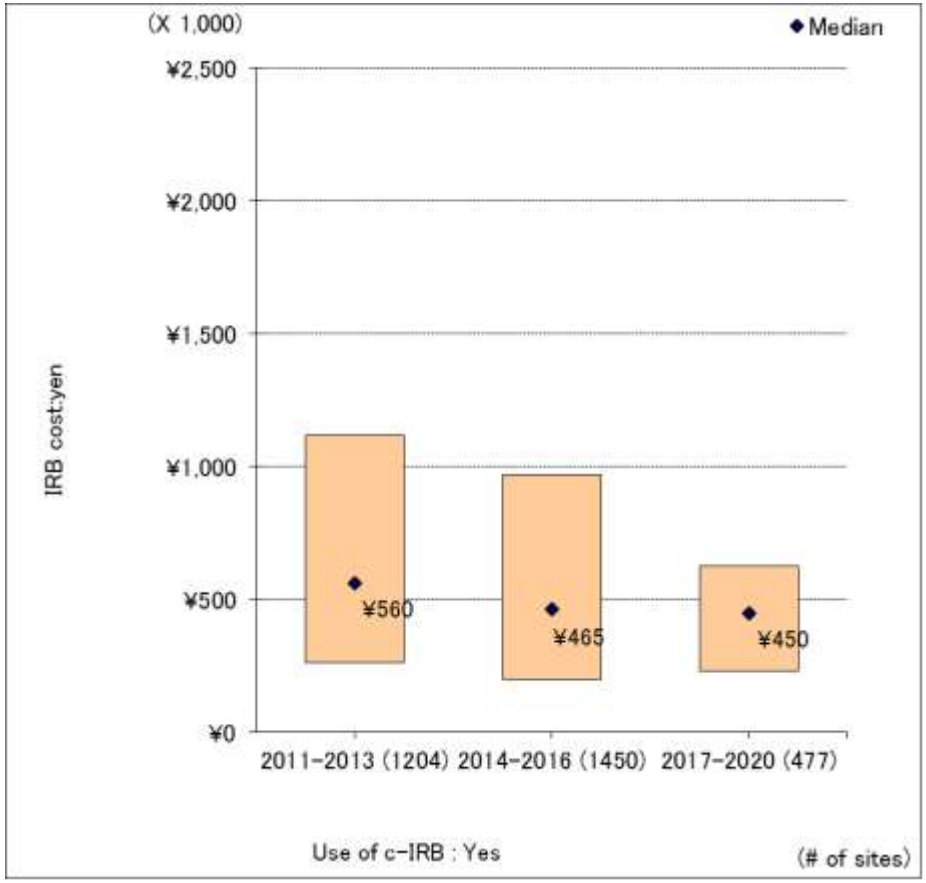
III-3-4 Methods of Payment by Type of Site

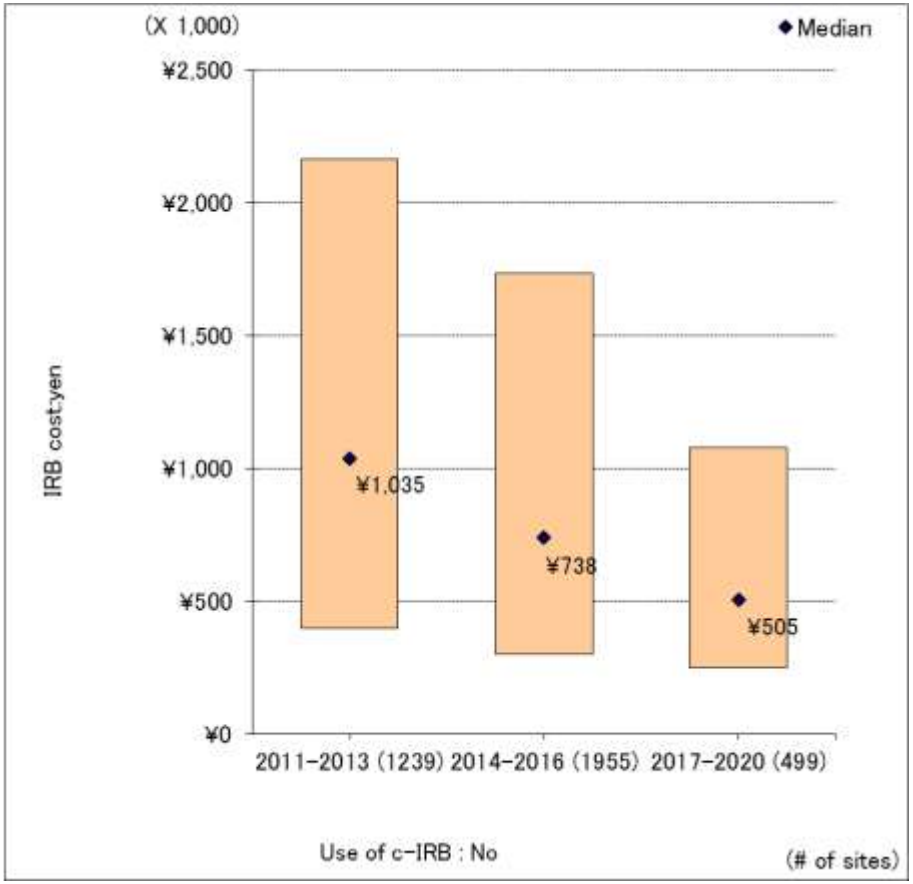


III-3-5 Implementation of Milestone Payment in Site by Type of Site



III-3-13-1 IRB Cost: [Sub analysis] Utilization of c-IRB

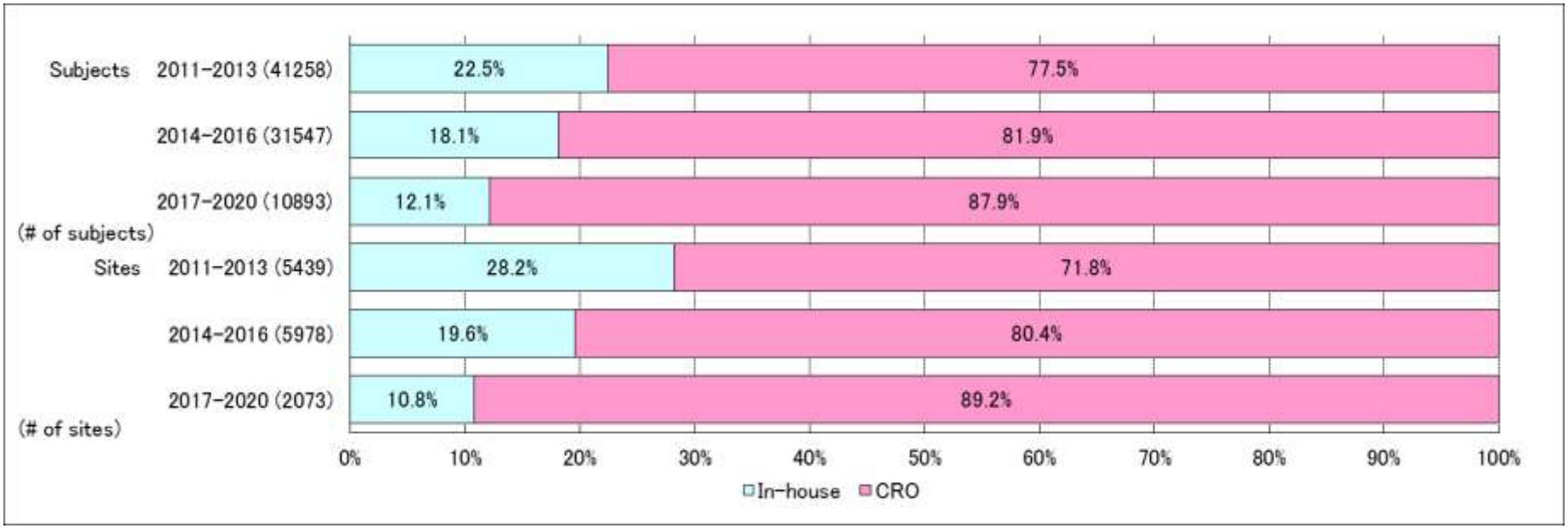




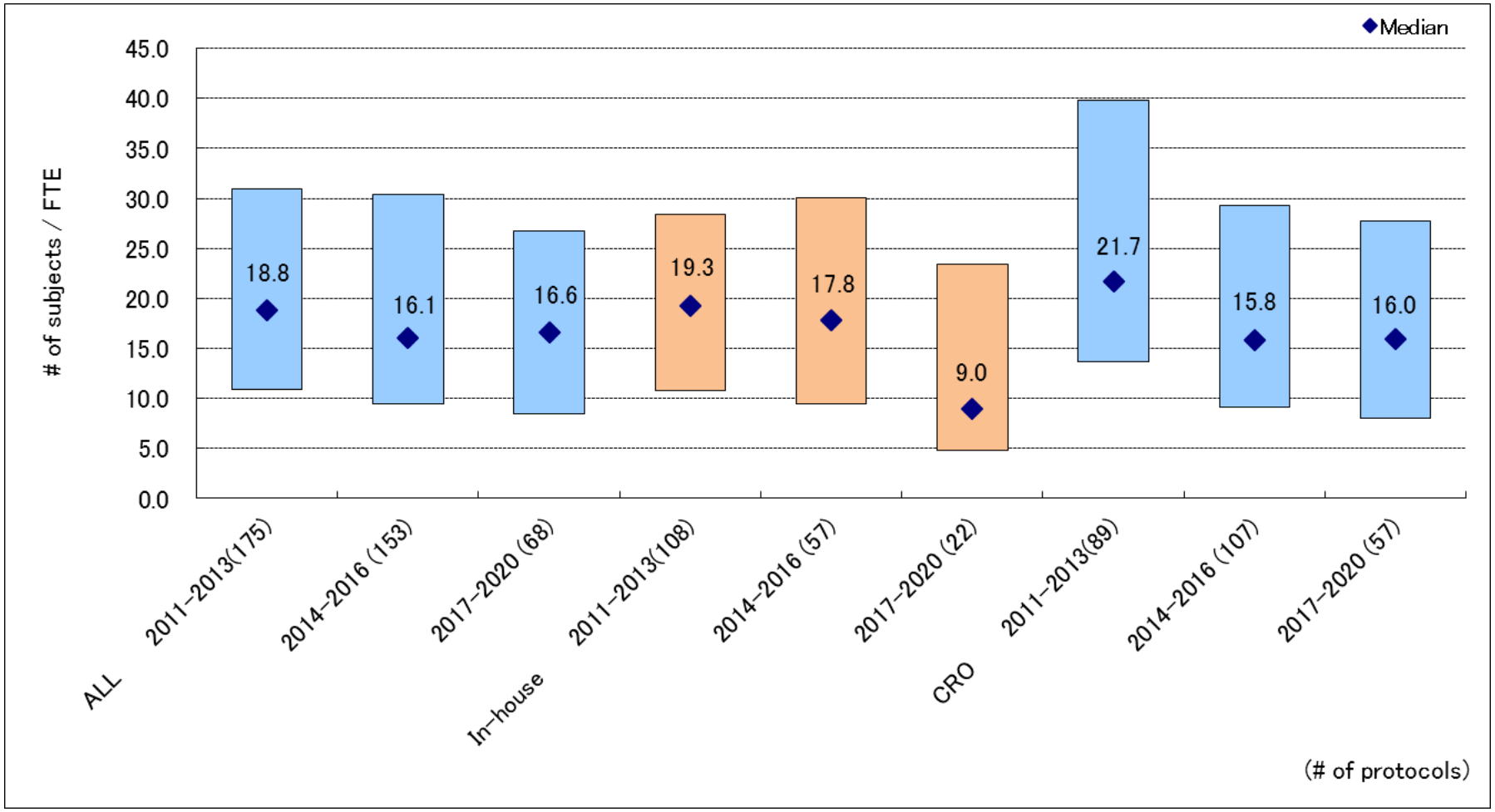
- Since this survey is performed on the basis of completed studies, special attention should be paid to non-inclusion of data of studies that takes a long time to complete (i.e., studies not completed at the time of the 2021 survey) particularly in years “2017-2020.”
- Due to the inappropriate error label on IRB costs in the previous (prior2017) survey form entry check, some of the IRB cost data may not have been properly collected in the before 2017 survey.

III-4 Monitoring Performance

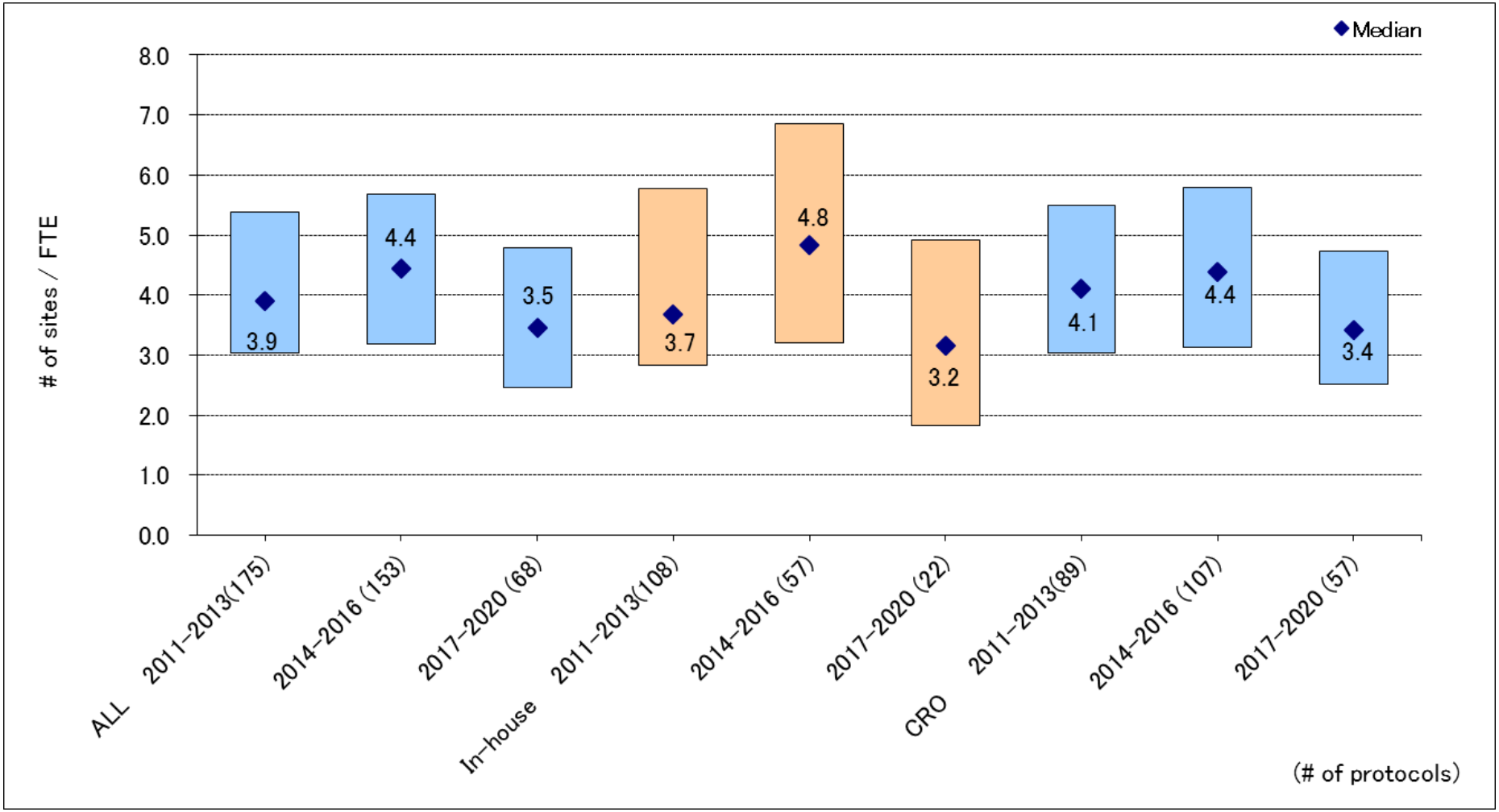
III-4-1 Proportion the Number of Enrolled Subjects and Sites by Affiliation



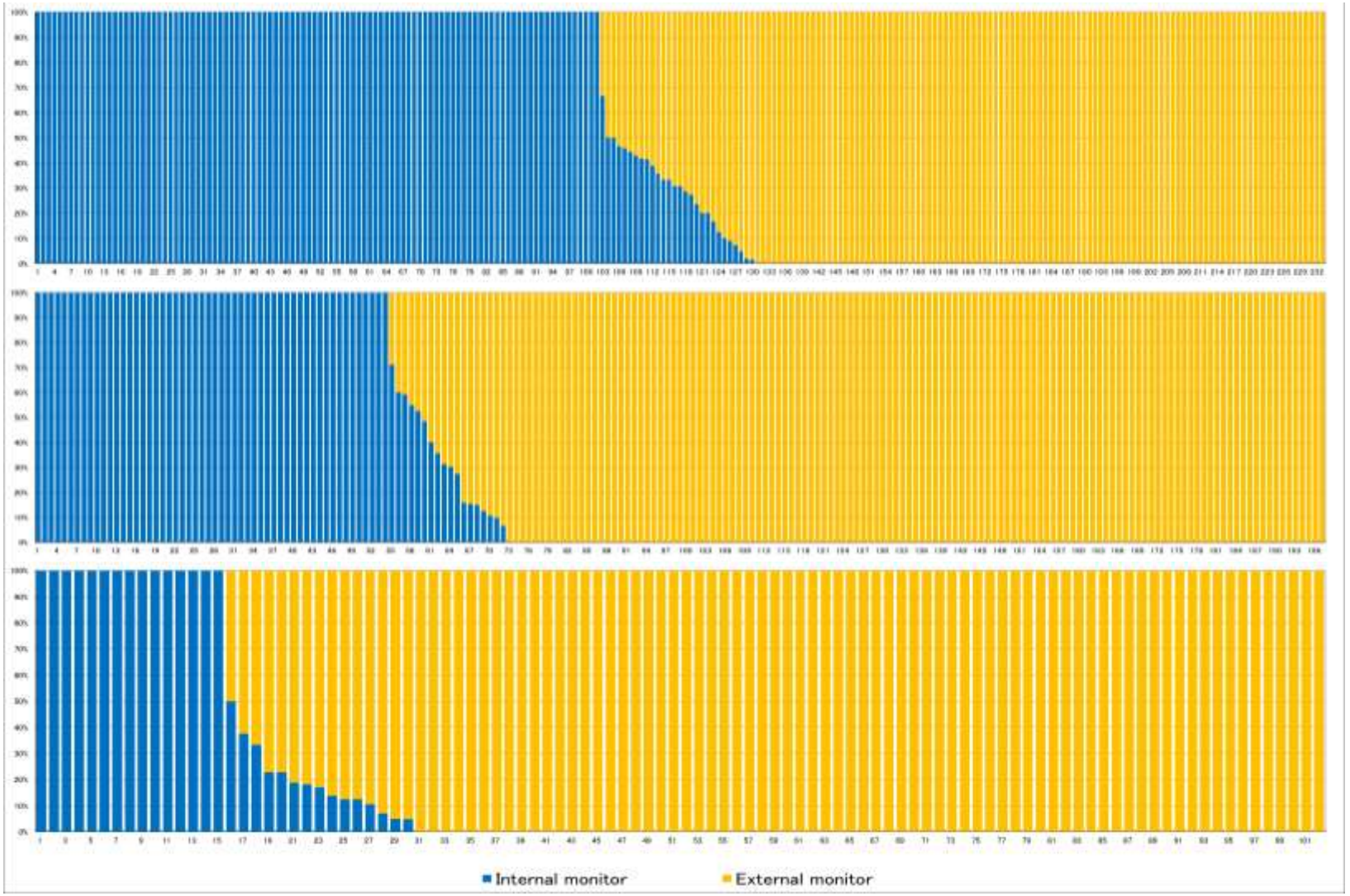
III-4-2 Number of Enrolled Subjects per Monitoring (FTE) by Affiliation



III-4-3 Number of Sites per Monitoring (FTE) by Affiliation

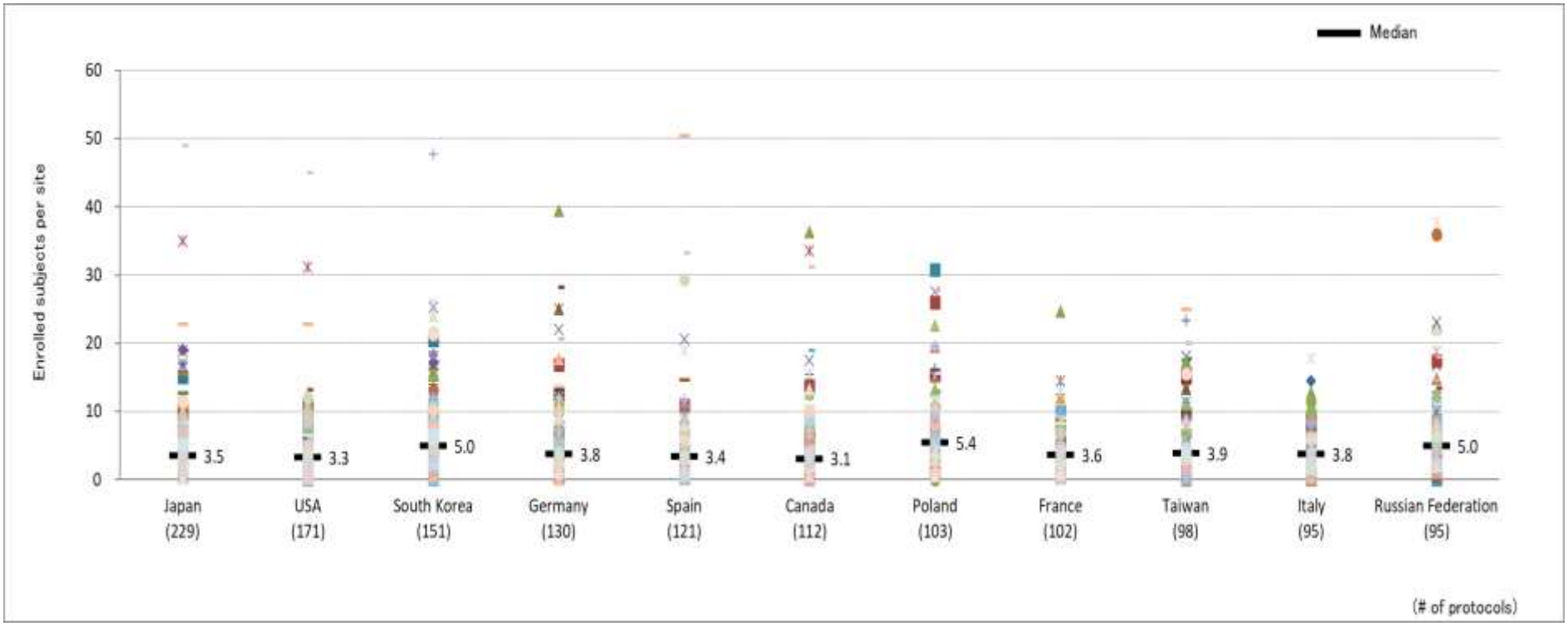


III-4-6-2 Proportion of CRA Outsourcing in Total Sites

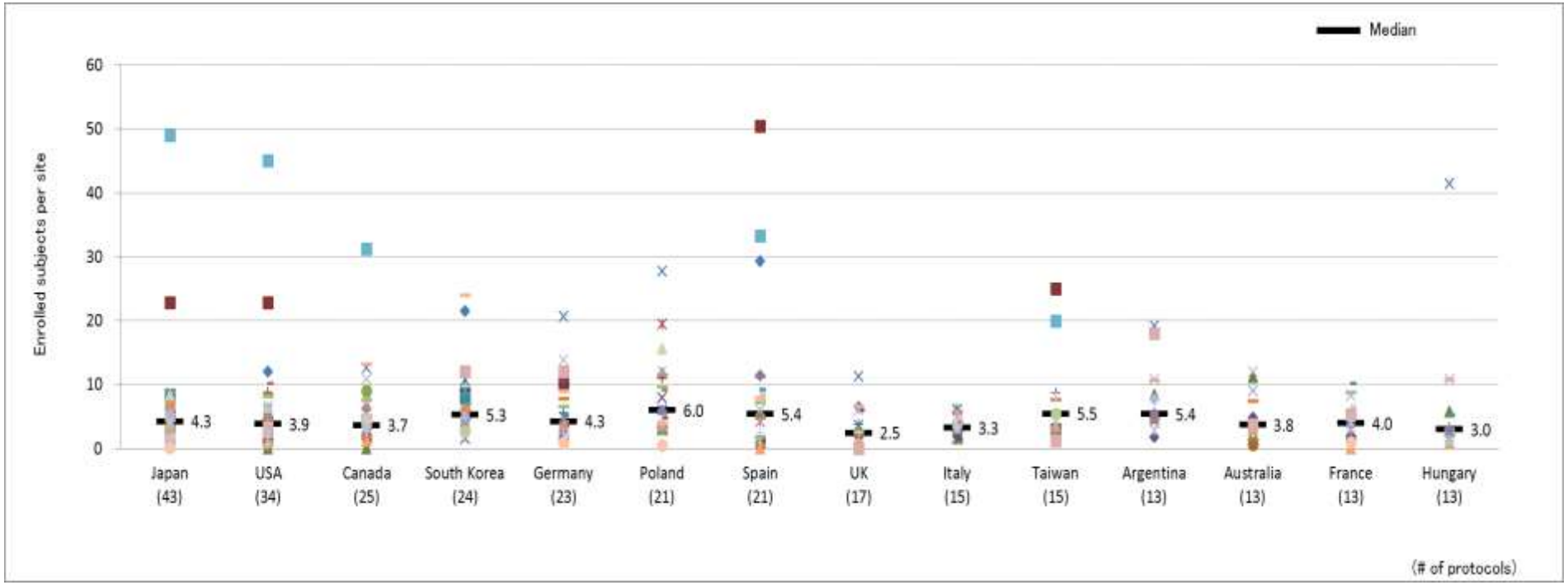


III-5 Global

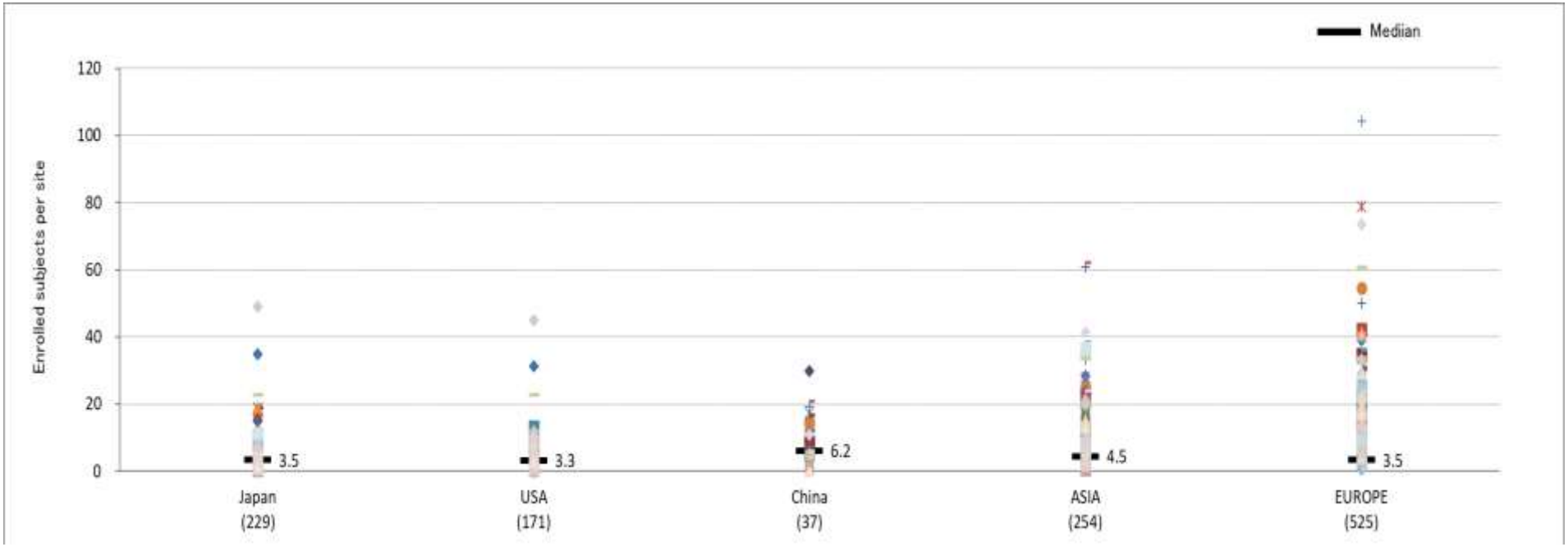
III-5-3-1 Number of Enrolled Subjects per Site by Most Frequent Top 10 Countries in Global Studies Scatter Plot



III-5-3-4 Number of Enrolled Subjects per Site by Most Frequent Top 10 Countries in Global Studies Scatter Plot (2017-2020)



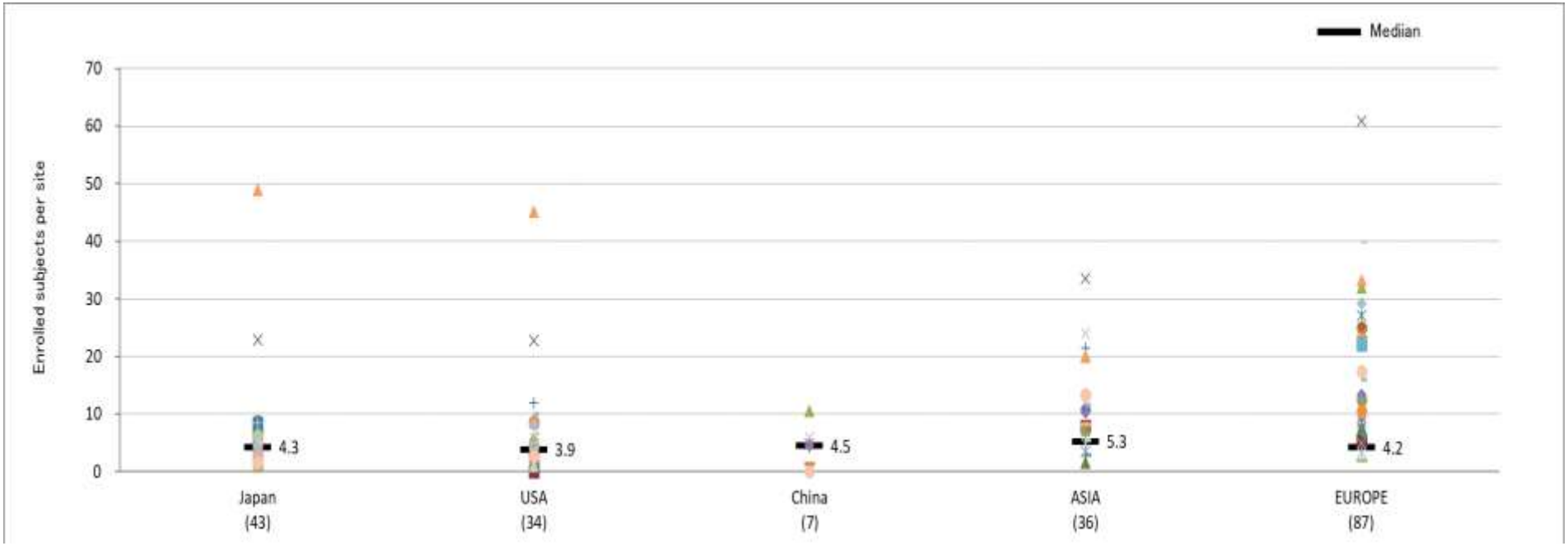
III-5-3-1-3 Number of Enrolled Subjects per Site by Region Classification in Global Studies Scatter Plot



(# of protocols)

ASIA : Hong Kong, South Korea, Taiwan EUROPE : France, Germany, Italy, Spain, UK

III-5-3-1-3-1 Number of Enrolled Subjects per Site by Region Classification in Global Studies Scatter Plot (2017-2020)

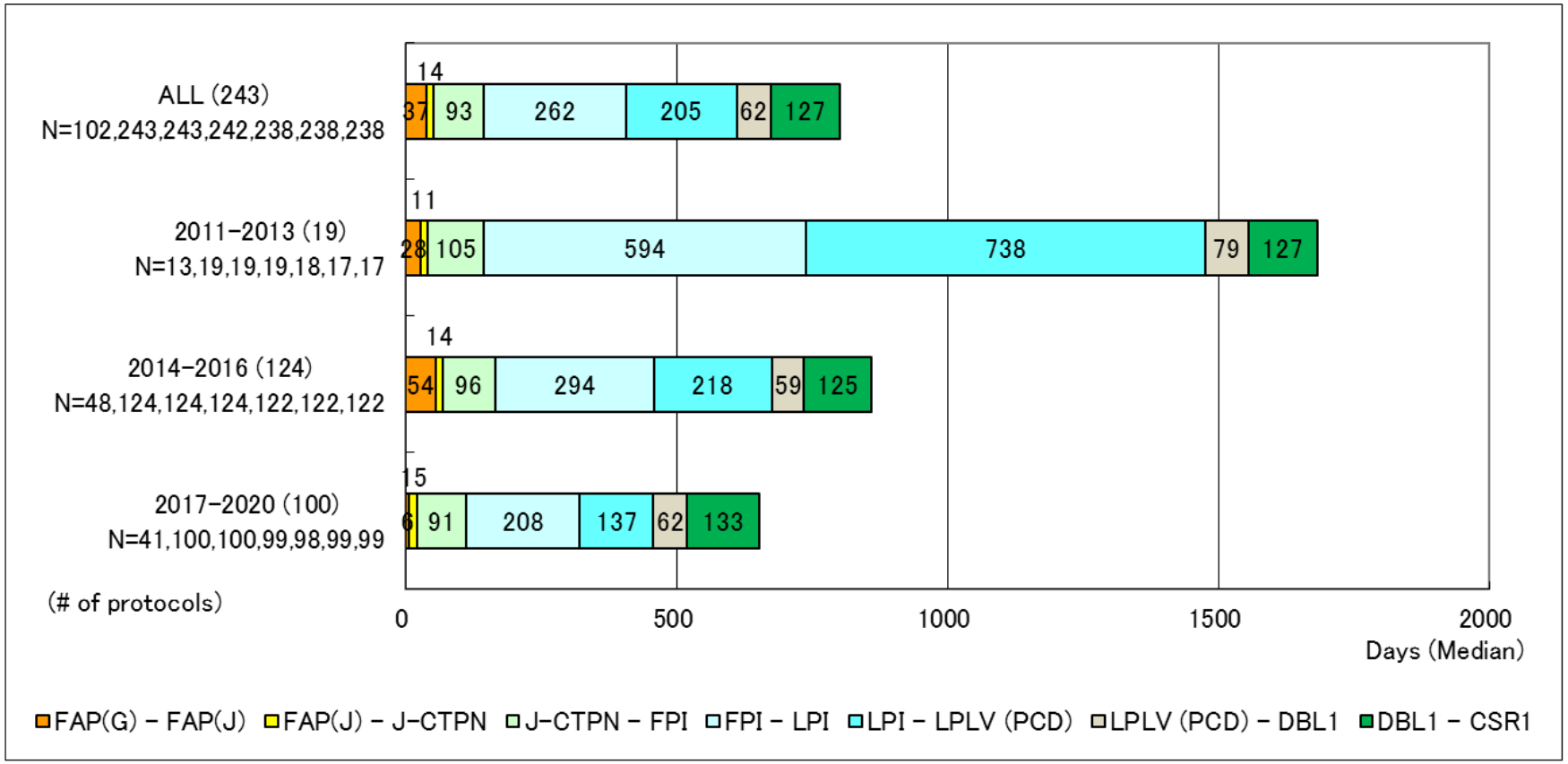


(# of protocols)

ASIA : Hong Kong, South Korea, Taiwan EUROPE : France, Germany, Italy, Spain, UK

III-6 Cycle time

III-6-1 Cycle time



N numbers are listed from left to right: FAP (G)-FAP (J), FAP (J)-J-CTPN, J-CTPN-FIP, FIP-LPI, LPI-LPLV (PCD), LPLV(PCD)-DBL 1, DBL 1-CSR 1.

FAP: Final Approved Protocol FAP (G) – FAP (J) shows a difference in the number of days in global studies between overseas and Japan.

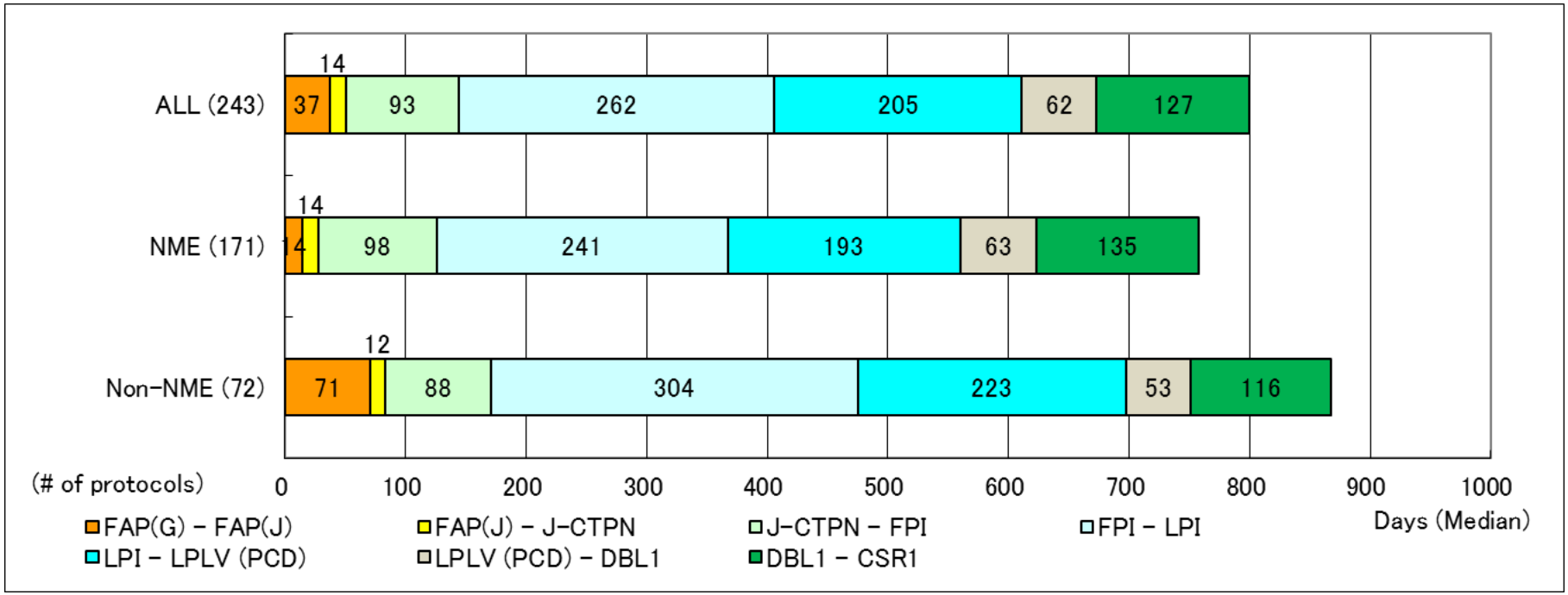
CTPN: Submission date of clinical trial notification, **FIP:** First Patient In, **LPI:** Last Patient In, **LPLV**: Last Patient Last Visit,

PCD: Primary Completion Date (When the study was still ongoing after filing an approval application, the date when the last subject was tested or intervened for the purpose of collecting final data on primary results in accordance with a pre-designated protocol)

DBL 1: Database Lock 1 (The date when the database for approval application is fixed), **CSR 1**: Clinical Study Report 1 (The date when the clinical study report for approval application is completed)

- Please note that there are few protocols for the segment of years 2011-2013 due to the start of this survey item in 2021.
- Since this survey is performed on the basis of completed studies, special attention should be paid to non-inclusion of data of studies that takes a long time to complete (i.e., studies not completed at the time of the 2021 survey) particularly in years “2017-2020.”

III-6-5 Cycle time by type of NME (2011-2020)



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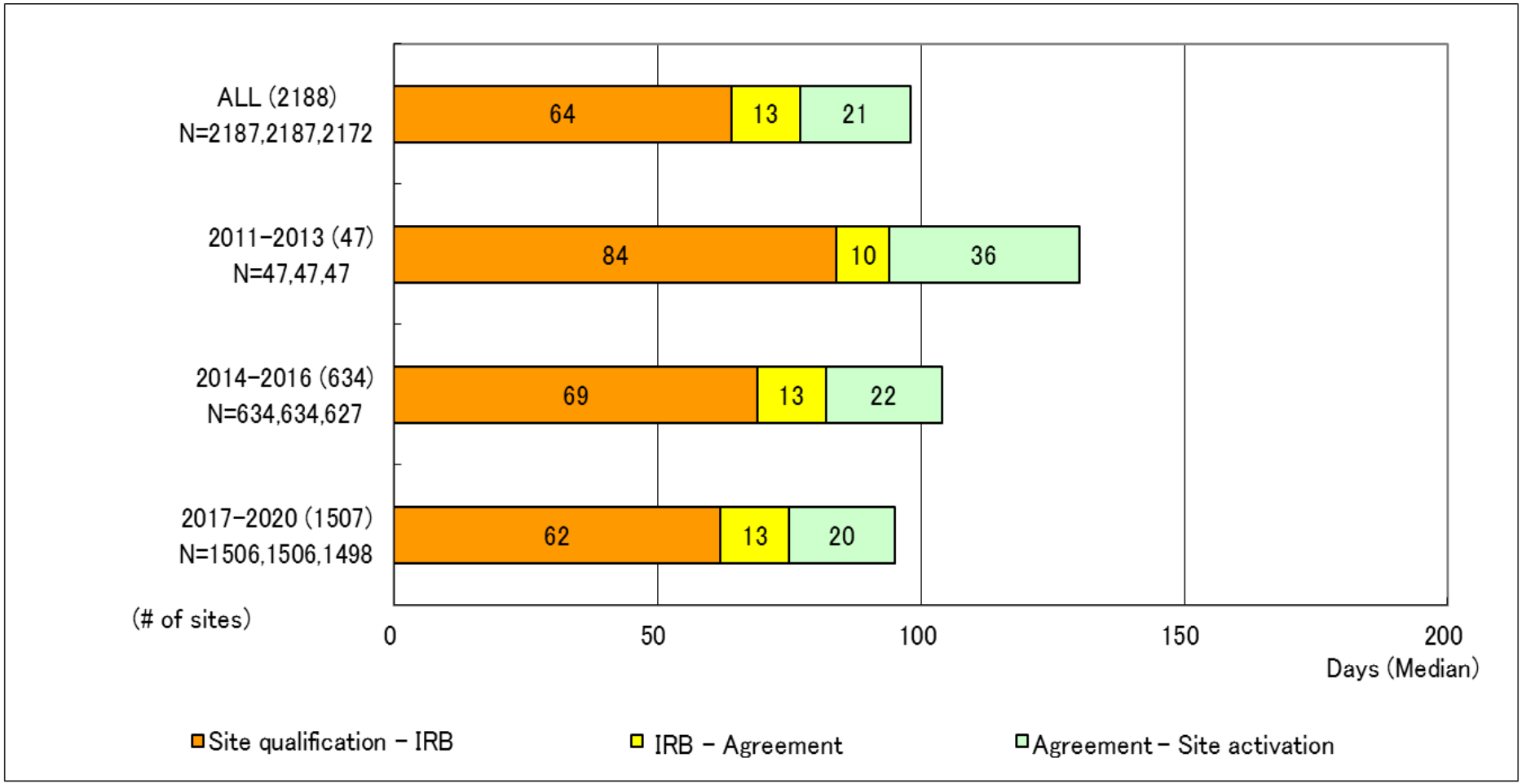
DBL 1: Database Lock 1 (The date when the database for approval application is fixed), **CSR 1**: Clinical Study Report 1 (The date when the clinical study report for approval application is completed)

III-6-6 Days to Site Qualification – IRB – Agreement – Site Activation

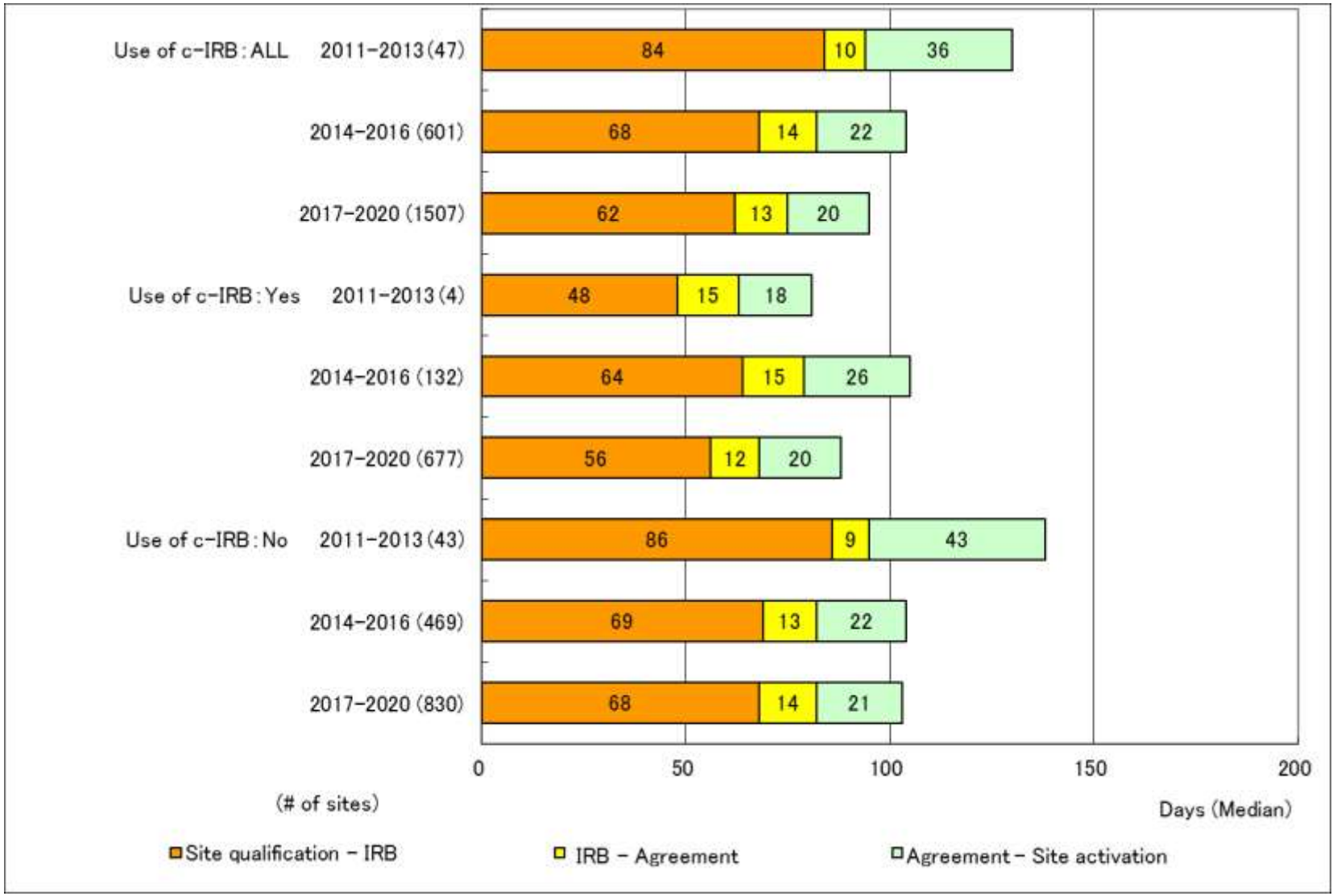


N numbers are listed from left to right: Site qualification-IRB, IRB-Agreement, and Agreement-Site activation.

Please note that there are few protocols for the segment of years 2011-2013 due to the start of this survey item in 2021.

Year : Year of Site qualification

III-6-8 Days to Site Qualification – IRB – Agreement – Site Activation by Central IRB



Please note that there are few protocols for the segment of years 2011-2013 due to the start of this survey item in 2021.

Year : Year of Site qualification

Ⅳ. Summary

III-1 Background

- ✓ Collected Data: 124 studies from 20 companies (FY2019: 133 studies from 19 companies)
- ✓ Monitoring method: Significant increase of 'RBM' and 'the methods other than 100%SDV (e.g., Sampling SDV) '.
- ✓ eCOA: Increased
- ✓ DCT: Performed in some items (ePRO/eCOA, Medical activities by local healthcare providers)

III-2 Enrollment

- ✓ The number of patients per site (median) was 3 patients: No change [continuing issue]

III-3 Cost

- ✓ Performance based only: Increased to 62%
- ✓ Implementation rate of milestone payment: Increased to approx. 63%
- ✓ IRB Cost: Decreasing trend, lower cost due to c-IRB usage

III-4 Monitoring Performance

- ✓ Number of enrolled subjects per monitor 1FTE : approx. 17 subjects [continuing issue]
- ✓ Number of sites per monitor 1FTE : 3.5 sites [continuing issue]
- ✓ "Number of in-house monitors" and "Number of CRO monitors" : The proportion of CRO monitors increased.

III-5 Global

- ✓ Improved the number of enrolled subjects per site in globally.
- ✓ The number of enrolled subjects per Japan site is similar to that in the US, EU, and China, but smaller than that in the Asia [continuing issue]

III-6 Cycle time

- ✓ NME Cycle time is shorter than non-NME.
- ✓ In the case of Central IRB usage, the period from the date of Site qualification to the date of IRB is short.

Secondary use of this result

This report has been prepared by R&D Head Club member companies by bringing together data in order to understand current clinical trial environment in Japan. Please note the following instruction when you use this material for the secondary use.

Preliminary actions for secondary use

- Please let the R&D Head Club secretariat know below contents by contact form in the R&D Head Club home page（https://rdhead-club.com/contact/）
  - User (name, affiliation, opportunity to use)
  - Where used (applicable pages and purpose of use*）

Ex.）
Name：Ichiro Suzuki
Affiliation：ABC Pharma K.K.
Purpose for ues：Oral presentation in OOO annual meeting, MMM/DD/YYYY
Data of use：Slide #18
Introduction on current clinical cost in Japan

How to describe Source Data

- Source：R&D Head Club Clinical Trial Performance Survey 2021 https://rdhead-club.com/

*：It is to confirm that there is no discrepancy with the perception of R&D Head Club, and does not restrict secondary use.