外資系企業における製造販売後調査（PMS）の傾向
～ PhRMA / EFPIA 合同調査結果より ～

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COI開示：演題発表内容に関連し、発表者らに開示すべき利益相反はありません。

【目的】PhRMA及びEFPIA加盟会社における製造販売後調査（PMS）実施状況について調査を行い，外資系企業での近年のPMSの傾向やその変化を分析するとともに今後の展望を考察する。

【方法】PhRMA加盟会社及びEFPIA薬事部会加盟会社を対象に，2023年度（2023年4月～2024年3月）に承認された新医薬品のPMSの実施状況について，2024年4月にアンケート調査を実施し，集計結果に基づき分析した。また，過去と同じ調査項目の経年的な傾向に加え，DB調査やレジストリを利用した調査，全例調査の動向，調査のモニタリング体制，同意の取得，調査結果の公表に関する外資系企業の状況をまとめた。

【結果】

◆加盟会社のうち，20社よりPMSに関する回答を得た。2023年度，対象企業でのPMSは承認品目56品目中45品目（80%）で実施することとなった。この実施割合は，前年に比べ上昇している。実施するPMS（47調査中）のうち，特定使用成績調査は64%（30調査），一般使用成績調査は23%（11調査），データベース調査は13%（6調査）であり，2023年度も使用成績比較調査は実施されなかった。承認品目に対する調査種類の傾向については，前年と大きな違いは認められなかった。

◆全例調査は13品目15調査あり，2023年度に承認された品目で使用成績調査（一般使用成績調査，特定使用成績調査）を実施することになったうちの33%を占める結果であった。

◆2023年度，データベース調査を実施することとなった6調査のうち，5調査は企業からの提案で，1調査は規制当局との協議の上で実施された。6つのデータベース調査のうち，利用予定のデータベースは，1調査がレジストリ，1調査がMID-NET、3調査が商用データベースを予定していた。またDB調査を実施してきた上で，当初想定した内容とのギャップがあったと回答した会社は9社あり，主なギャップの内容はリソース増5社，コスト増3社等であった。

◆上述以外にも，PMS調査の概要として，目標症例数・調査期間や費用のトレンドや初回申請時の照会事項発出時期や実施計画書等の合意時期についても調査結果の発表を行う。

Trends in Post-Marketing Surveillance (PMS) in Foreign-Affiliated Companies

~ From the results of a joint PhRMA / EFPIA survey ~

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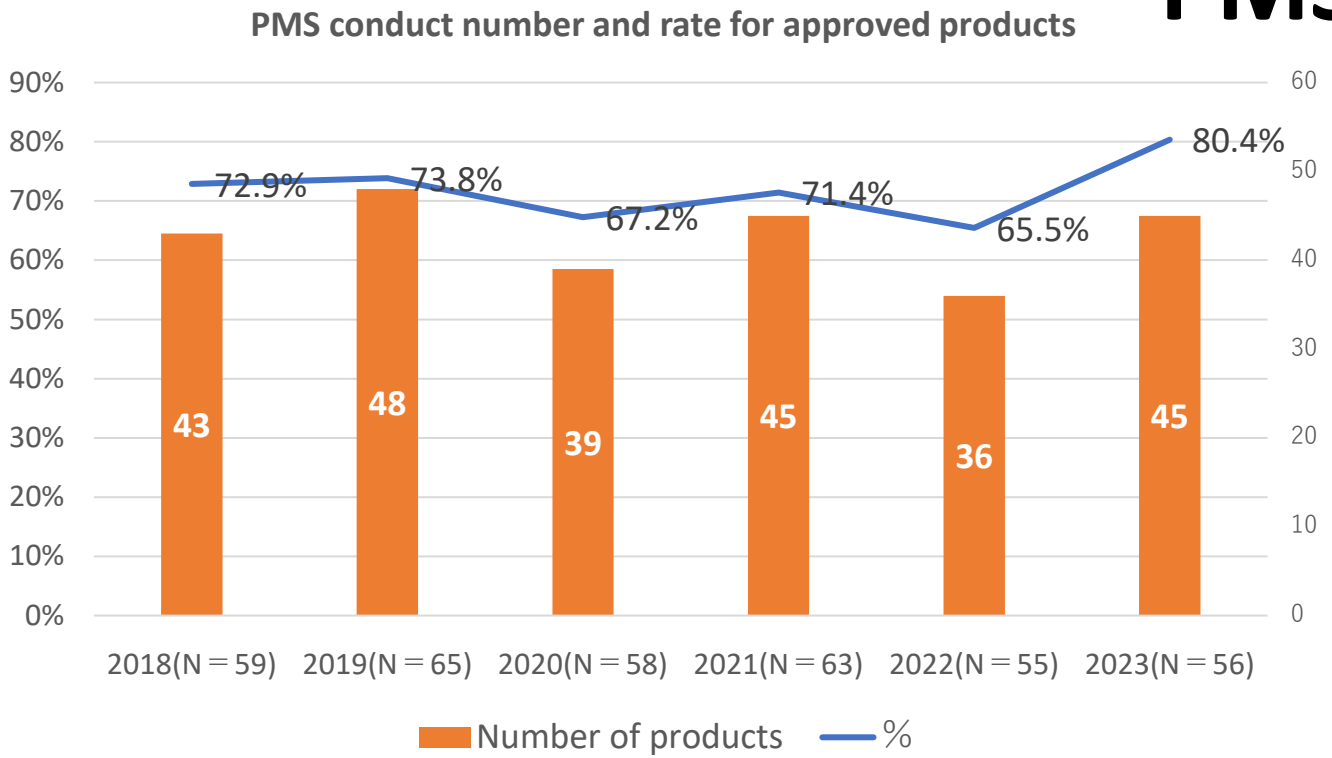
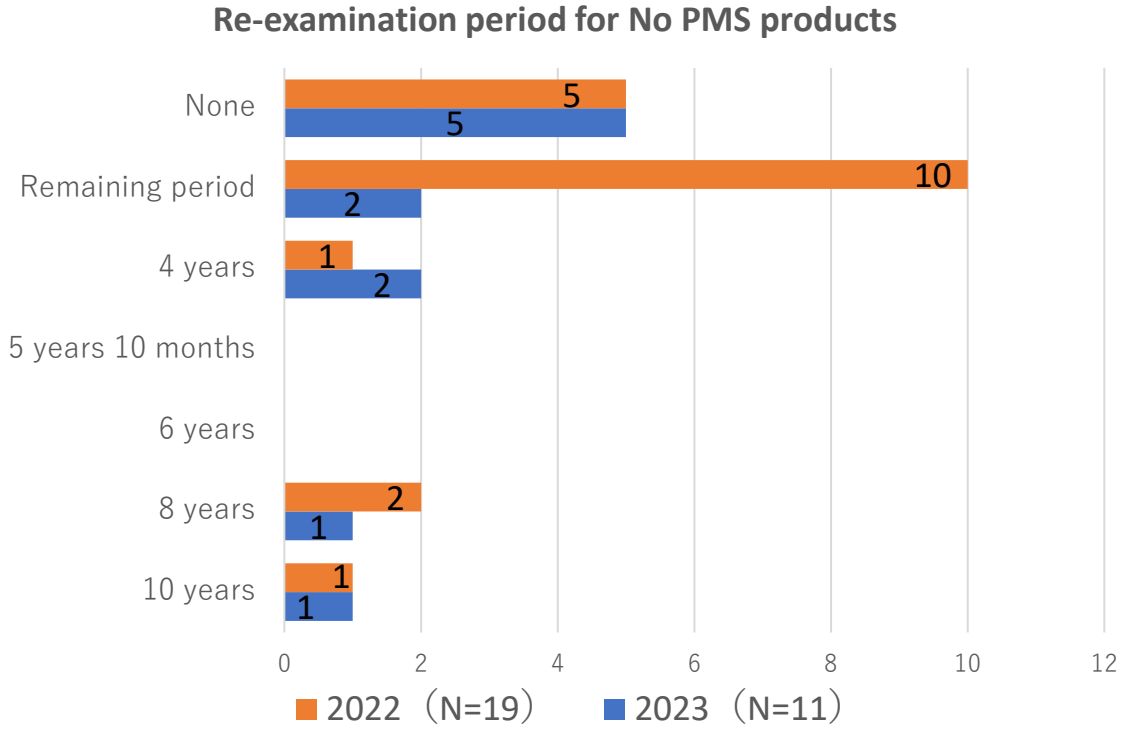
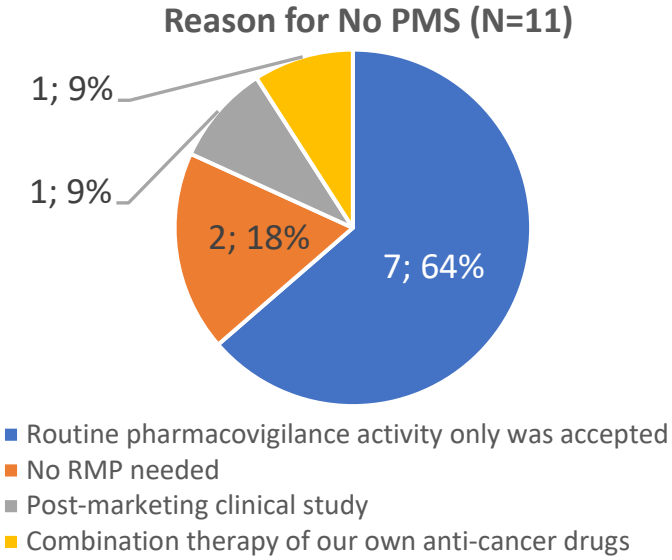
COI Disclosure: There are no conflicts of interest to disclose related to the content of the presentation by the presenters.

PMS

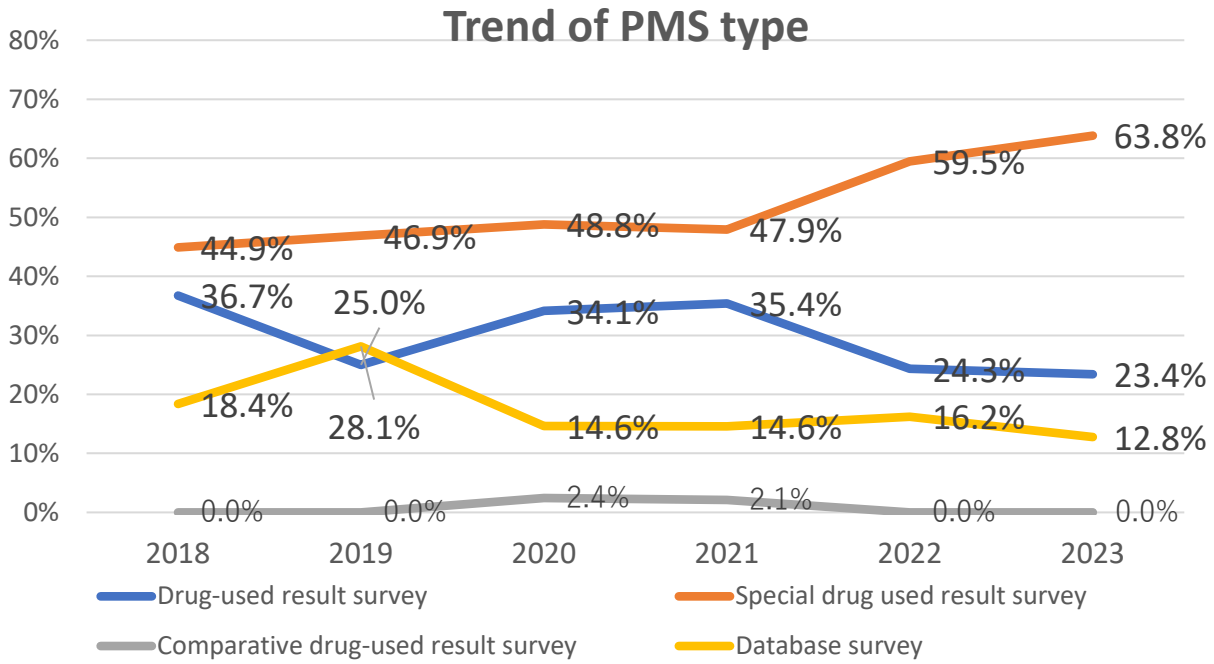




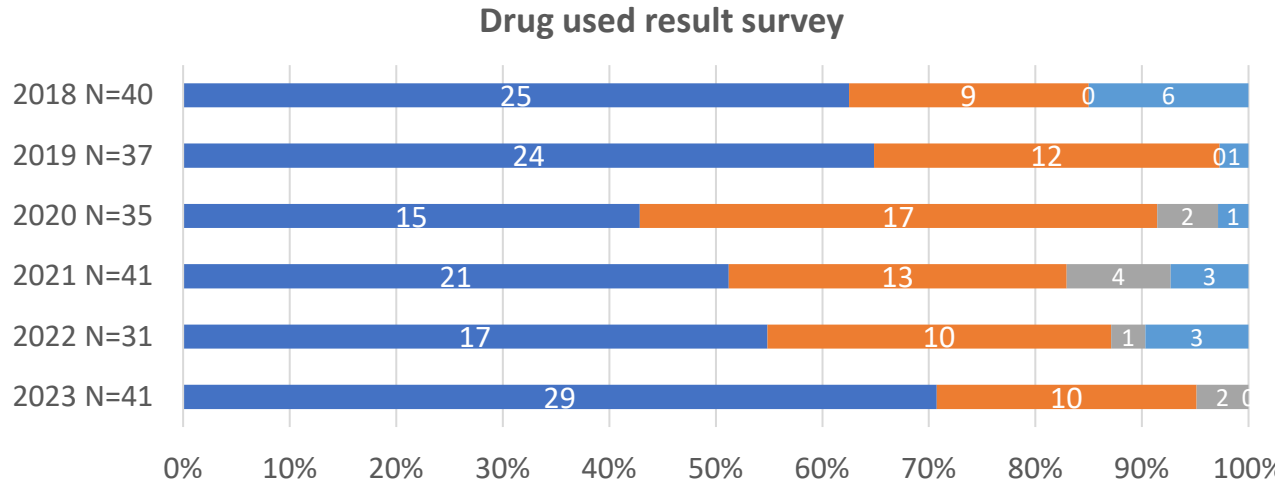


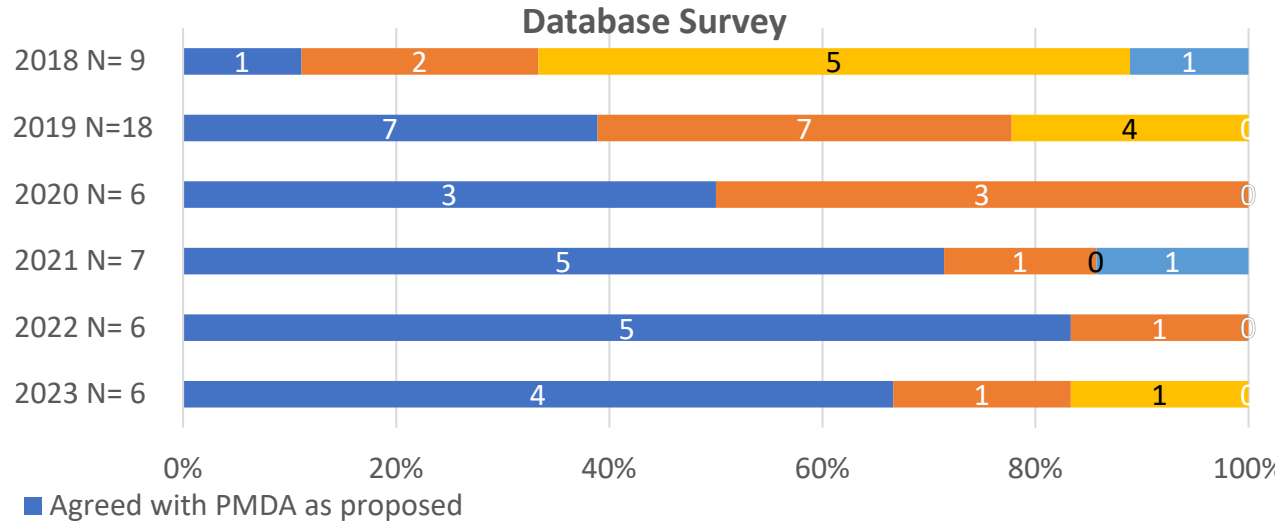
- PMS was conducted for 80.4% of approved drugs.
- Four of the 11 products with No PMS were granted a new reexamination.
- For most products without PMS, it was accepted that routine pharmacovigilance activities suffice.

PMS type trend and Background



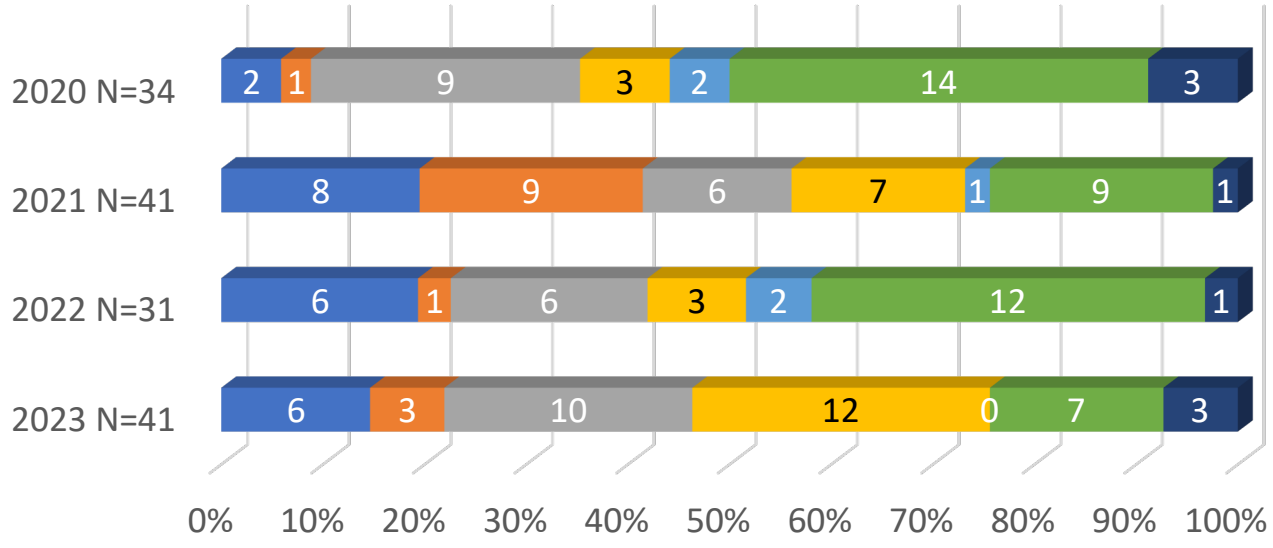
- The proportion of database surveys decreased in 2020 and remained in 2023.
- Of the six DB surveys, one was conducted in consultation with PMDA.
- The two survey is the cases of a DB survey being proposed, but it was later concluded to conduct a drug-used survey after discussion with PMDA.



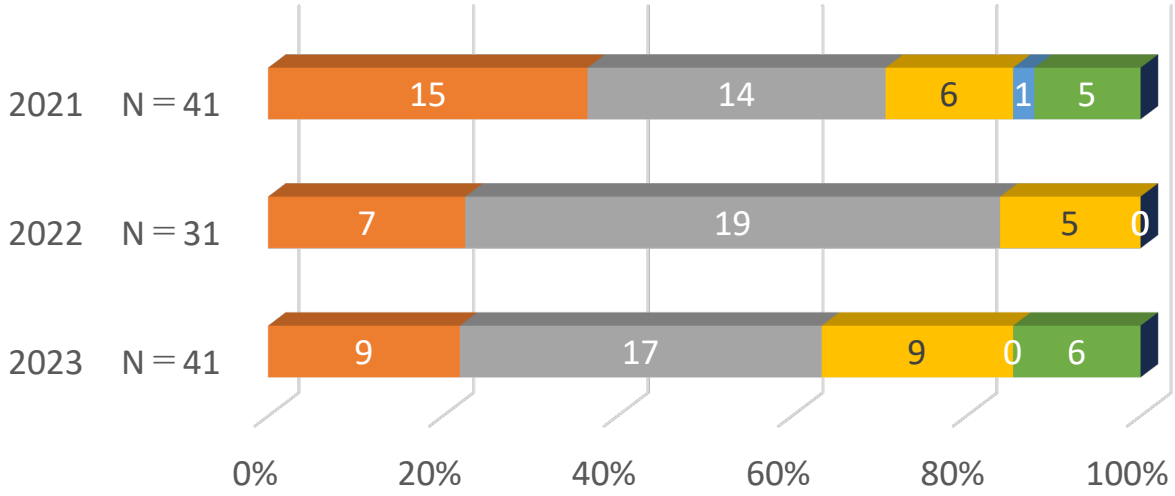


PMDA interaction timing in drug-used result surveys

First submission timing of PMS protocol

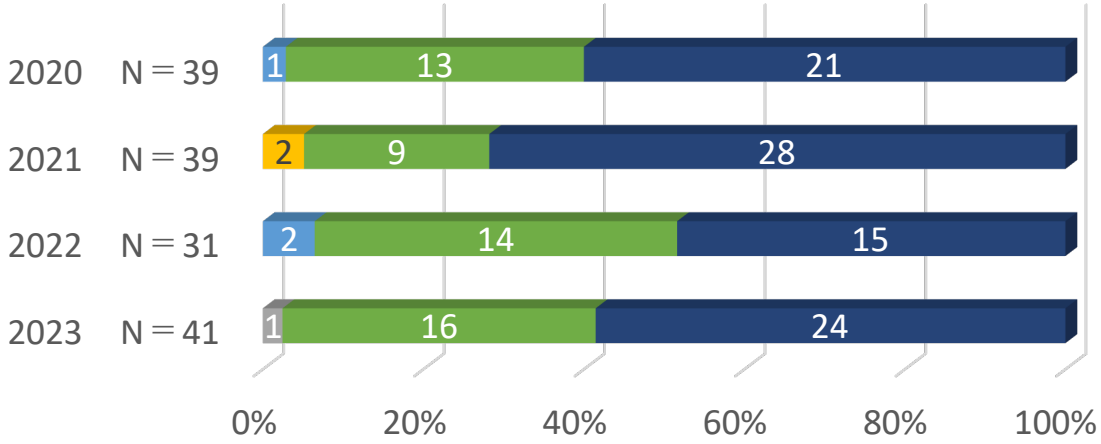


At the timing of receiving the first inquiries about PMS



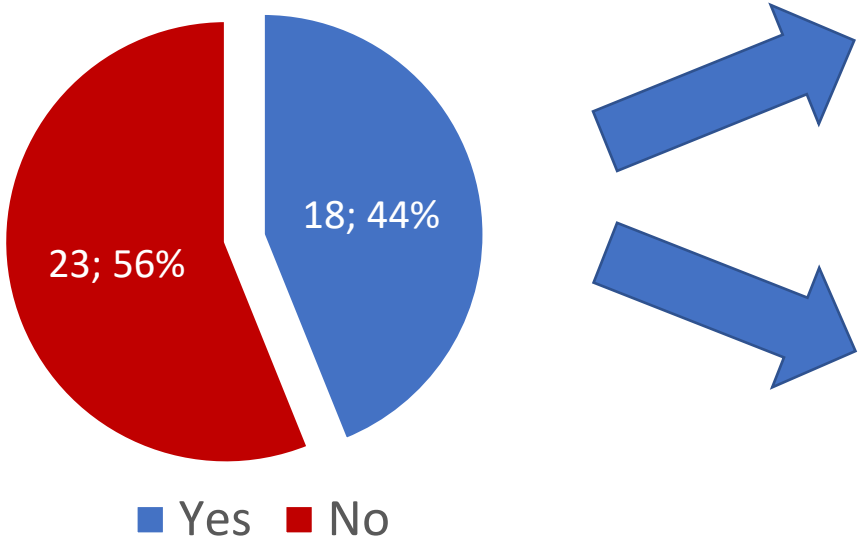
- 21% of the surveys had submitted protocols by the time of the initial interview.
- More than 60% of the first inquiries related to PMS were issued by the time of inquiries after initial meeting.
- In 58% of the surveys, the protocols, registration forms, and survey forms were agreed with PMDA after the BUKAI meeting.

Making agreement with PMDA about protocol, registration form and CRF



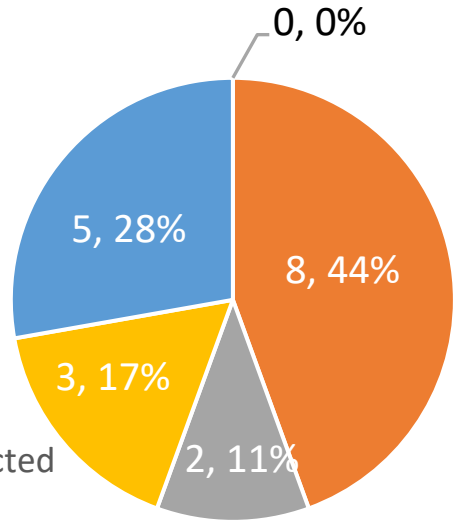
Drug-used result survey PMDA interaction -inquiries timing-

The queries requesting revisions to the implementation or design of RMP post-marketing surveillance (ex: number of cases, study design, etc., which have a significant impact on the company's budget) (N=41)

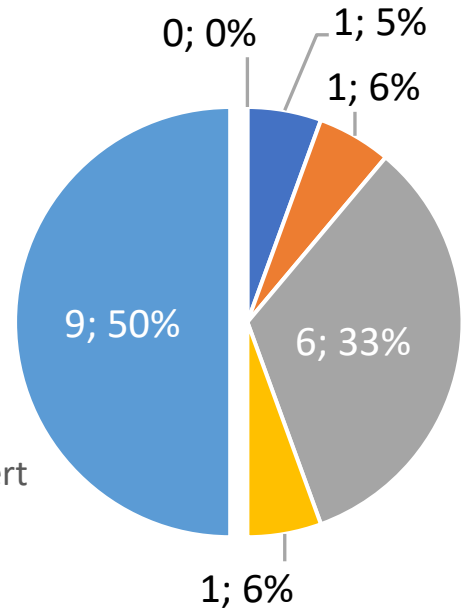


- In 44% of the cases, received inquiries affected the budget.
- In 55% of cases, inquiries were issued after expert meeting.

Item of inquiry(N=18)

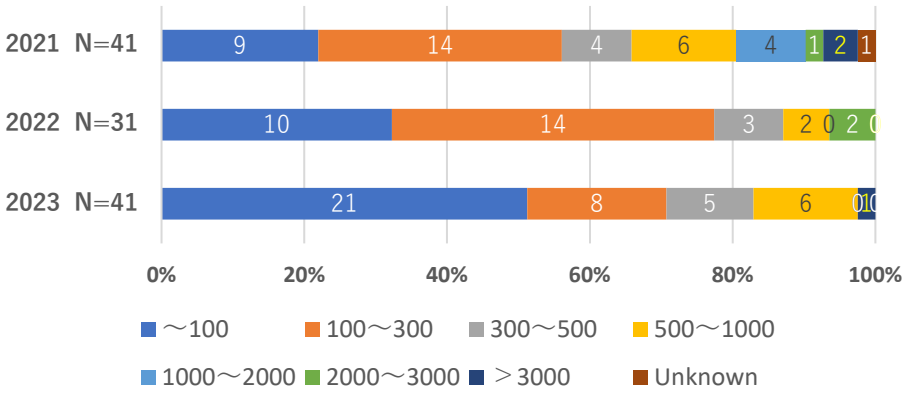


Timing of first inquiry （N=18）

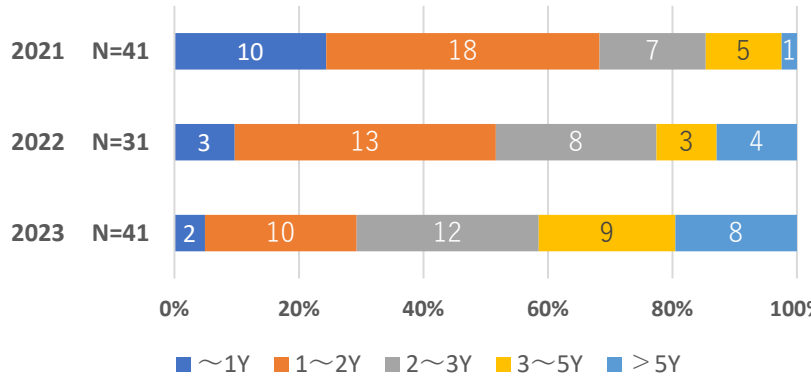


Drug-used/Special Drug-used result survey
-Survey number patients, period and cost-

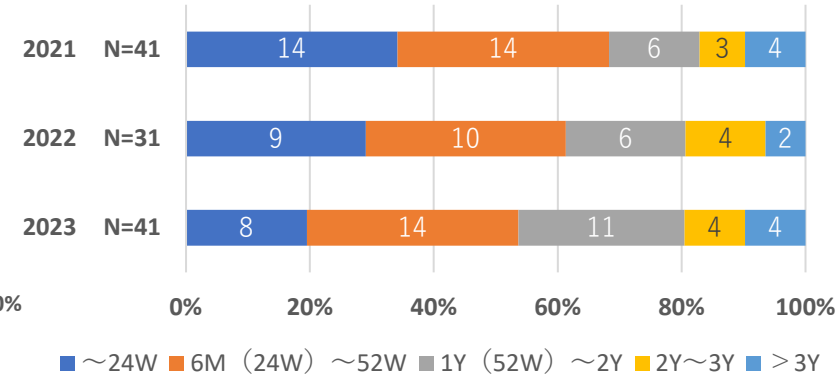
Number patients per PMS



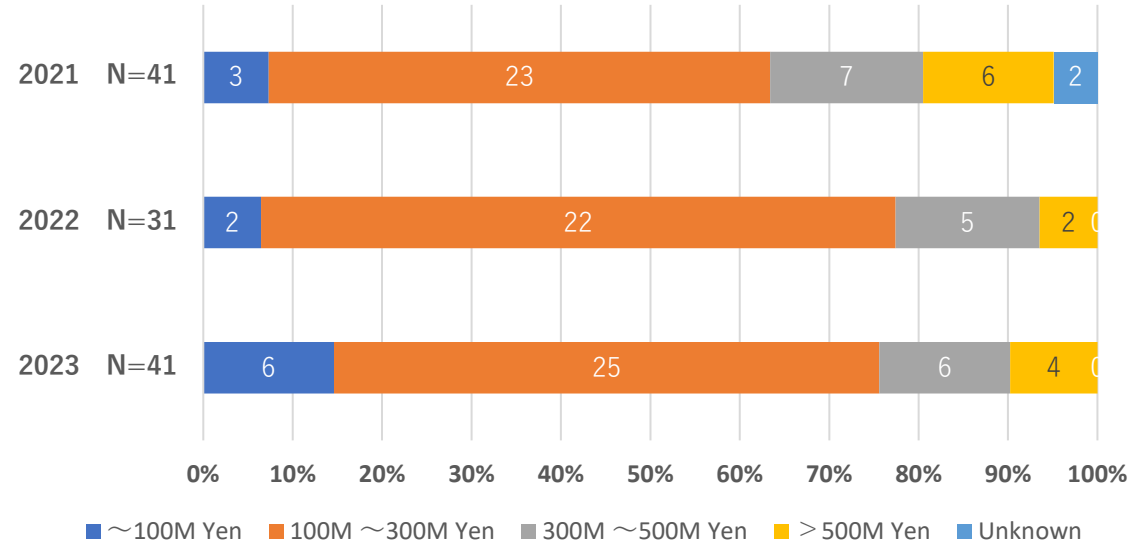
Enrollment period



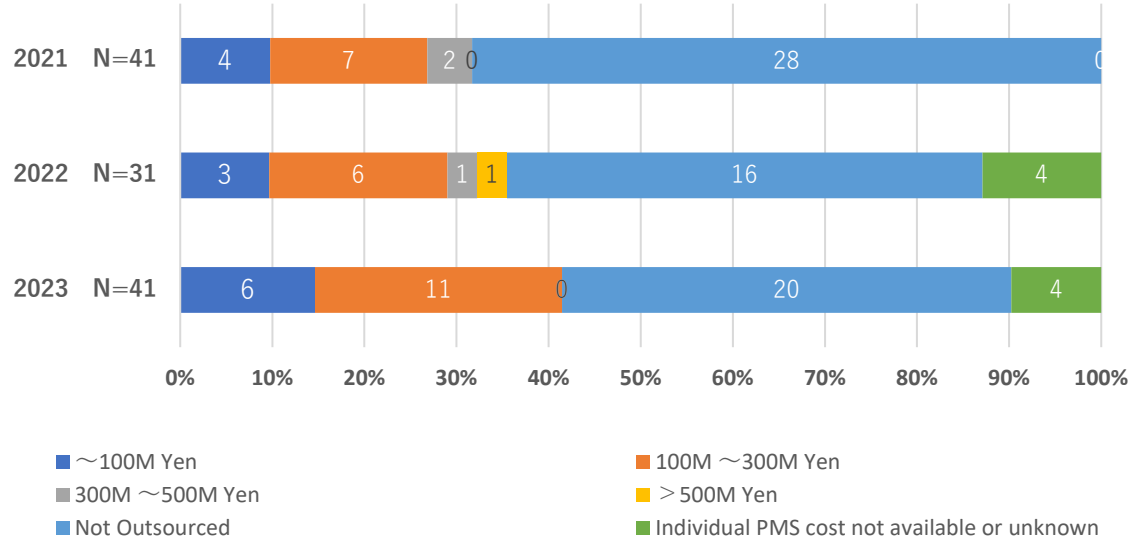
Observation Period per Patient



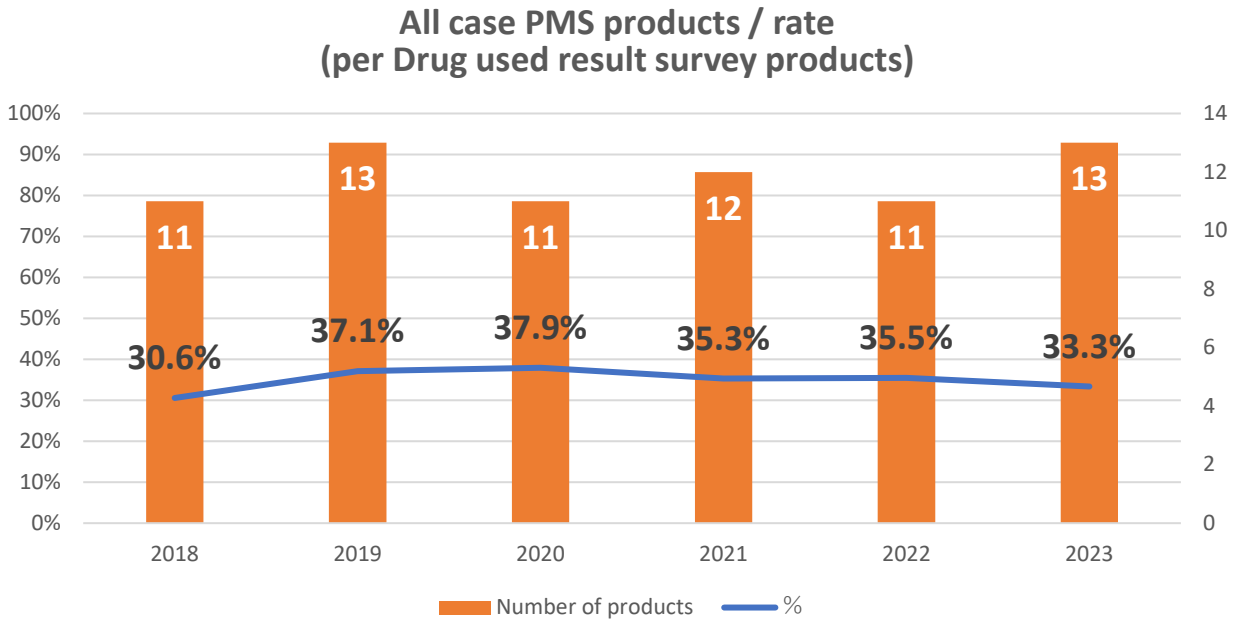
Cost of PMS (excluding of monitoring cost)

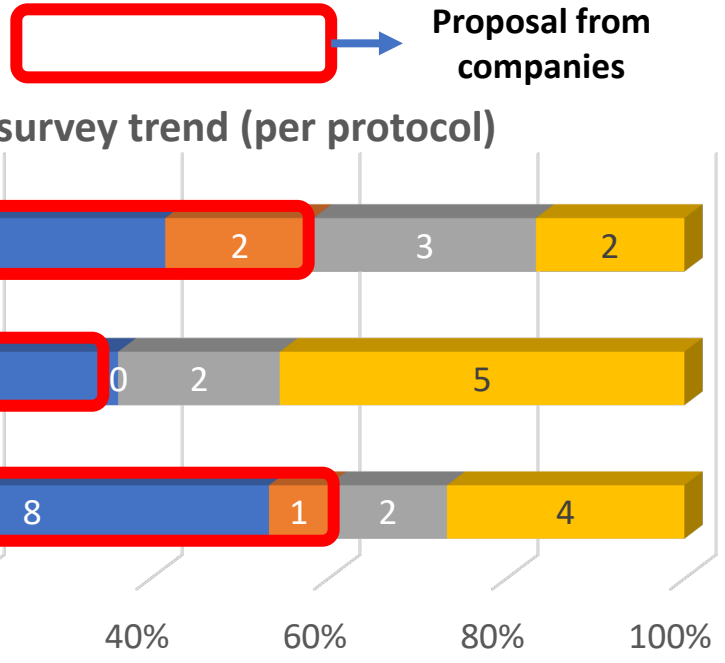


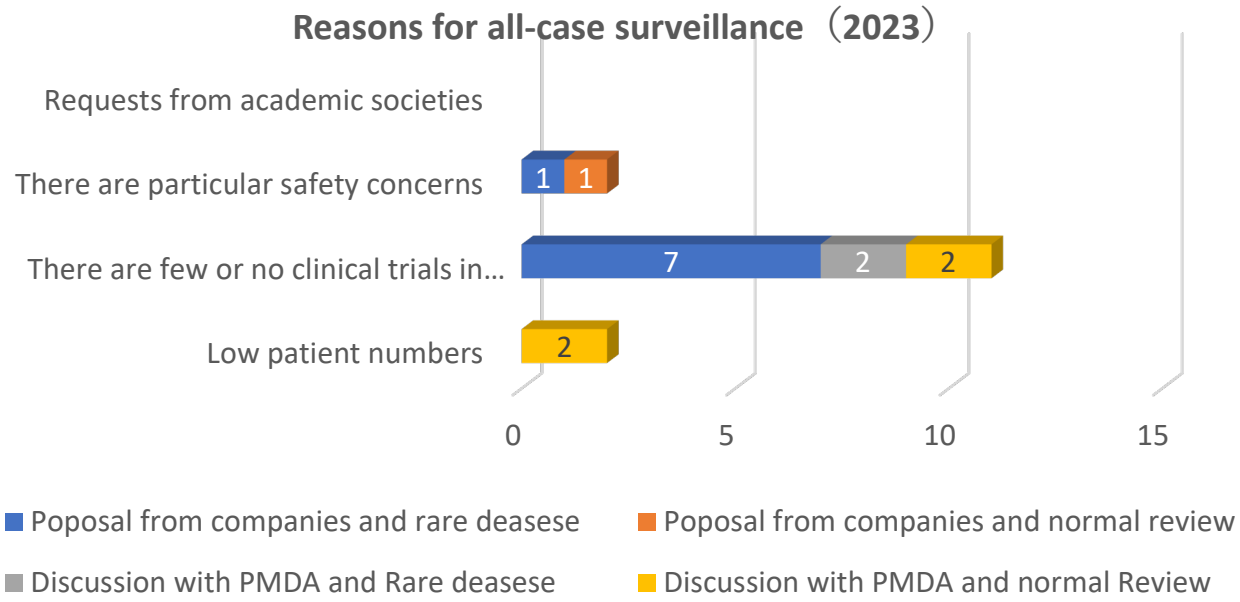
Monitoring Cost



All case survey trend





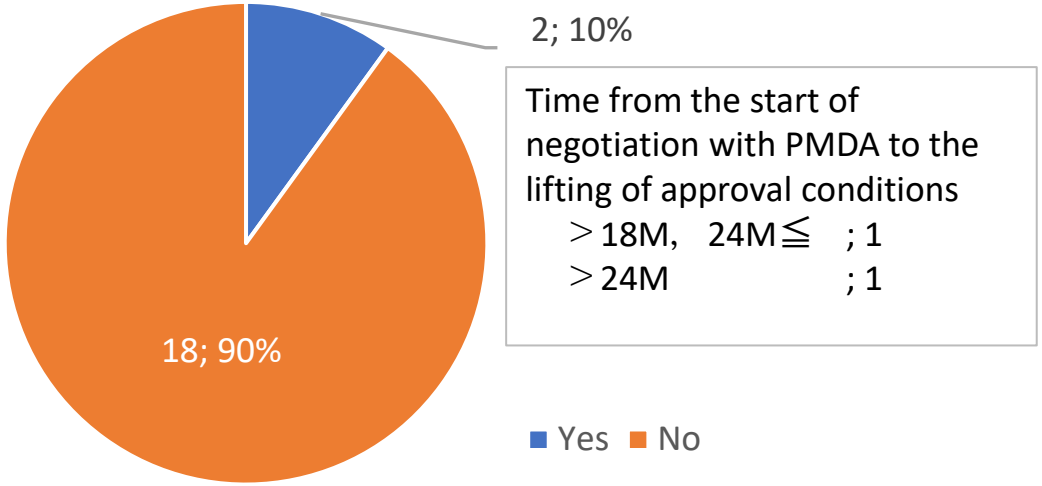


- More than one-third of the drug used results surveys conducted were all-case survey.
- Of the products under normal review, only one had the company itself propose all-case survey due to safety concerns.

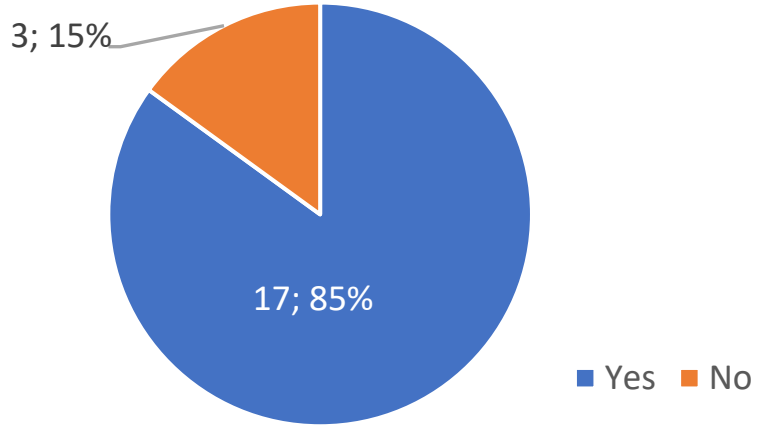
All case survey

-Lifting of approval conditions and implementation-

Lifted the condition for approval of all-case survey from 2023/04 to 2024/03 (N=20)

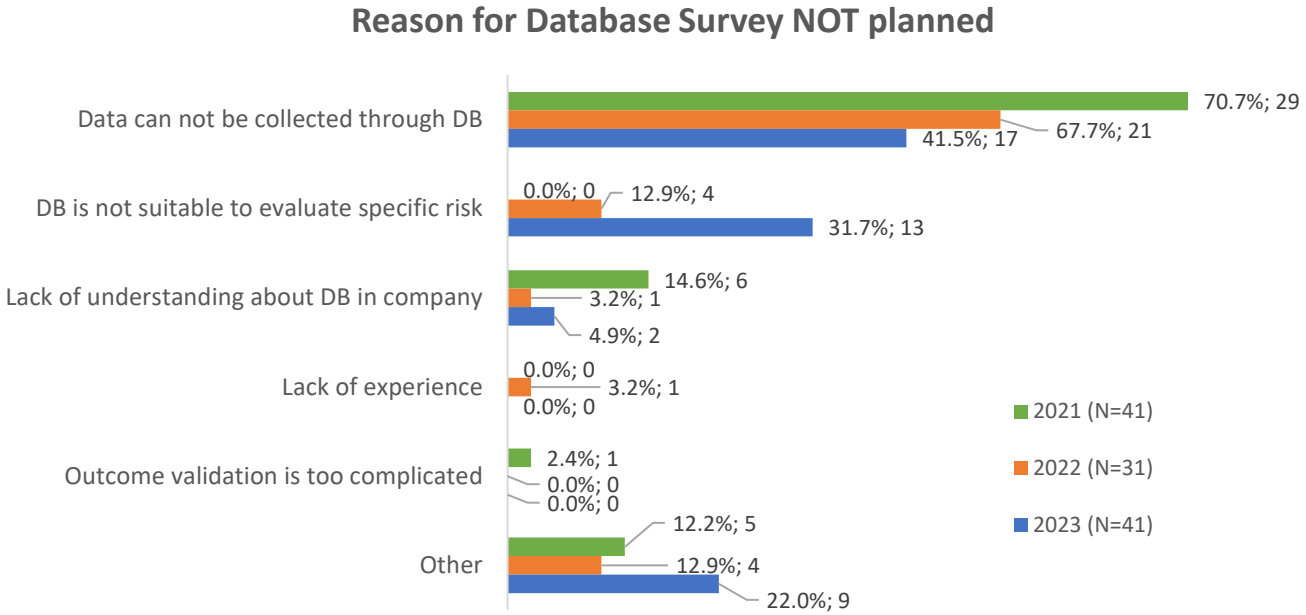


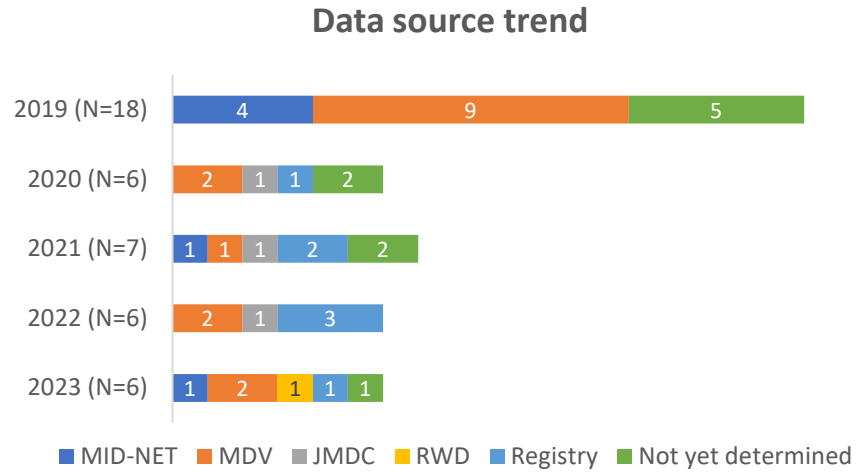
All-case survey conducted from 2022/04 to 2024/03 (N=20)

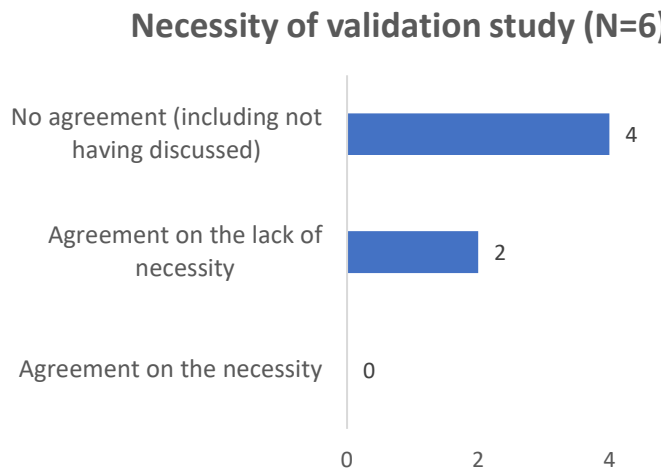


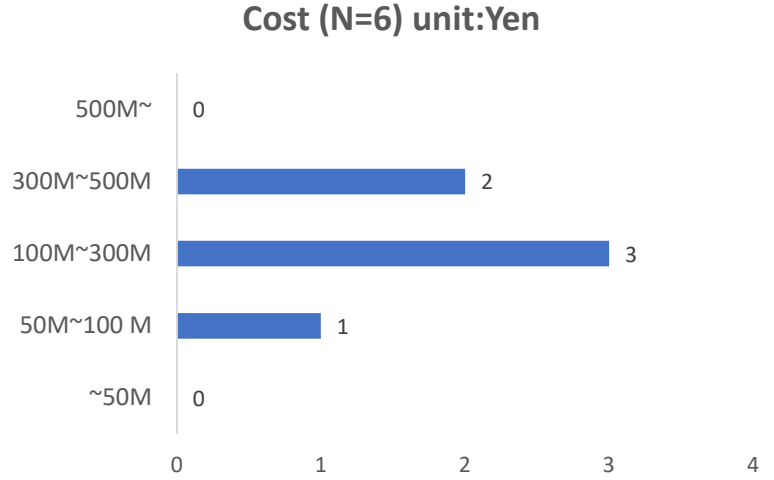
- Two companies experienced the lifting of approval conditions in FY2023. It took more than 18 months from consultation to lifting of approval conditions.
- In the past two years, 85% of the companies have conducted the all-case survey.

Characterization of database (DB) study





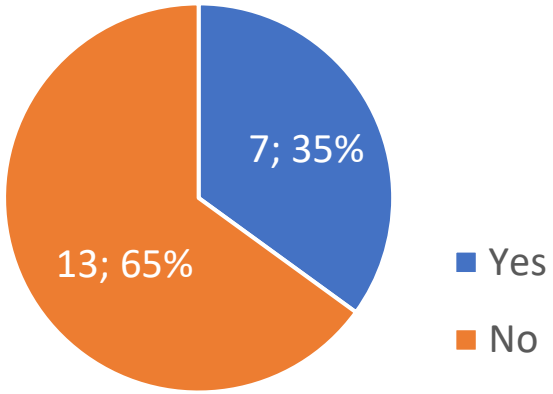




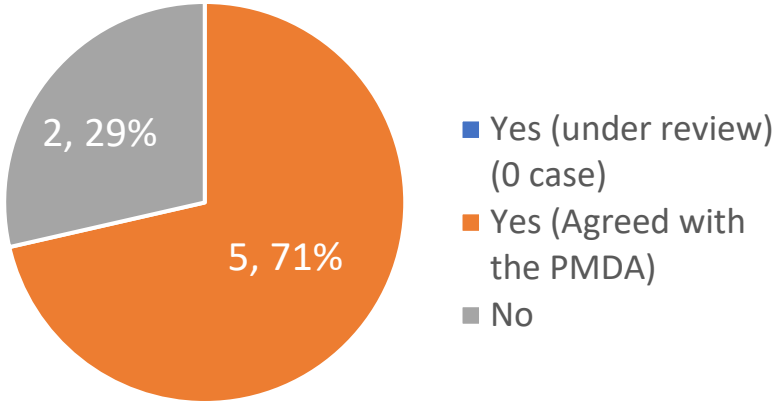
- Overall trend in the character of the studies has not changed.
- Over 500 million yen surveys have disappeared, and surveys in the range of 100 to 300 million yen have become the most common, indicating a tendency to reduce costs.

Database Survey Trend
-Registry, DB survey for safety purposes-

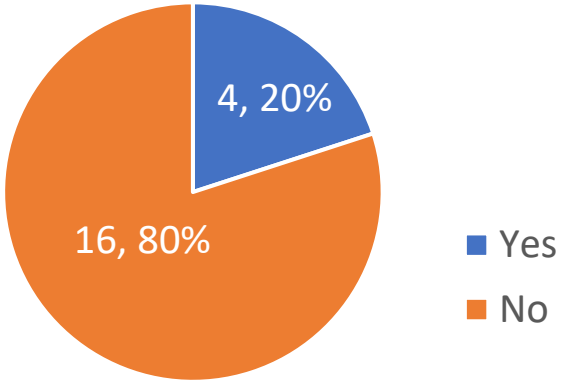
Any products for which the use of registry has been considered as a DB survey (N=20)



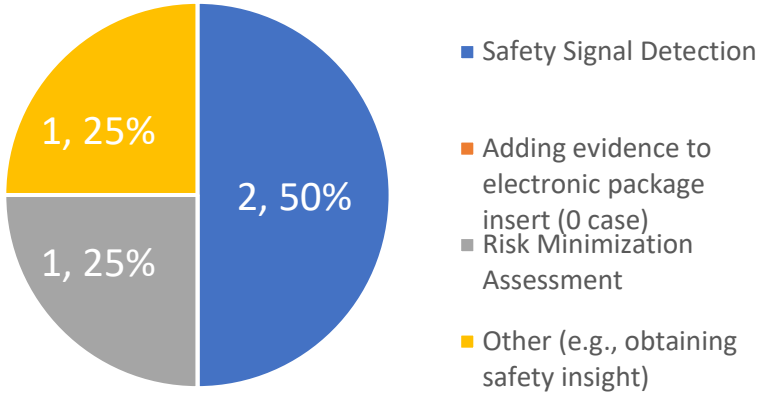
Submit the application for approval using the registry survey (N=7)



Considered/planned DB research outside of GPSP using medical information DB as an example of DB use? (N=20)



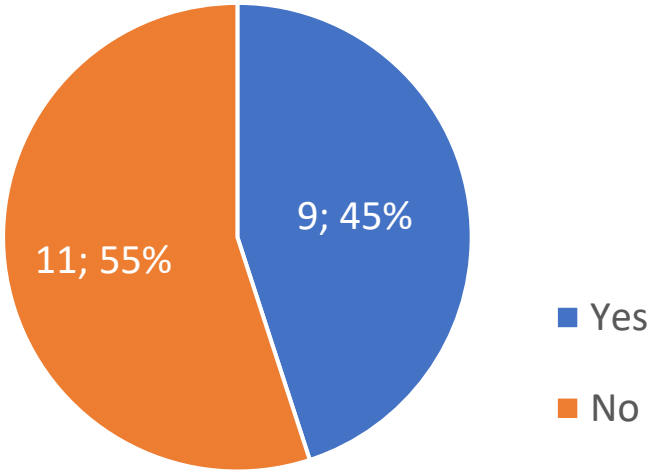
If "Yes" What examples of use cases have you considered? (N=4)



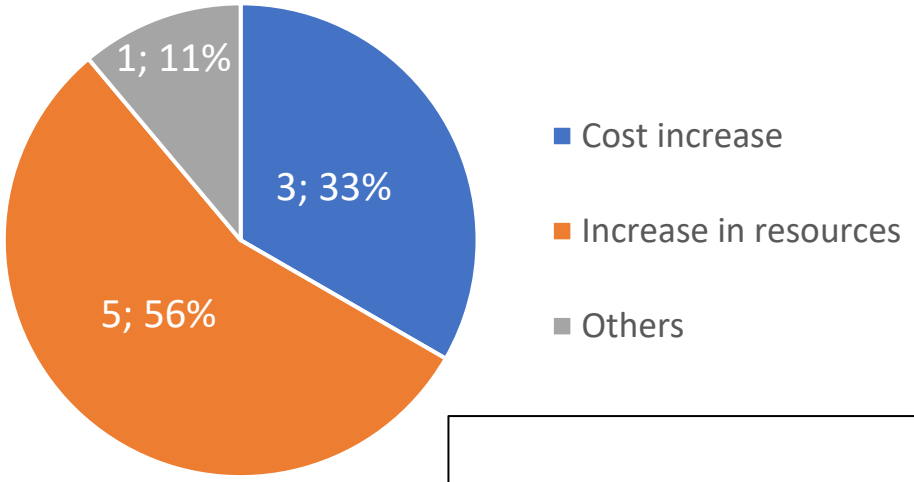
- 35% of companies have considered the utilization of registries.
- 20% of companies have considered or planned a DB study outside of the GPSP using a medical information DB for safety purposes.
  Examples were safety signal detection, risk minimization assessment and obtaining safety insight.

Database Survey Trend
-Gap-

Any gap with initial assumptions regarding the DB survey (N=20)



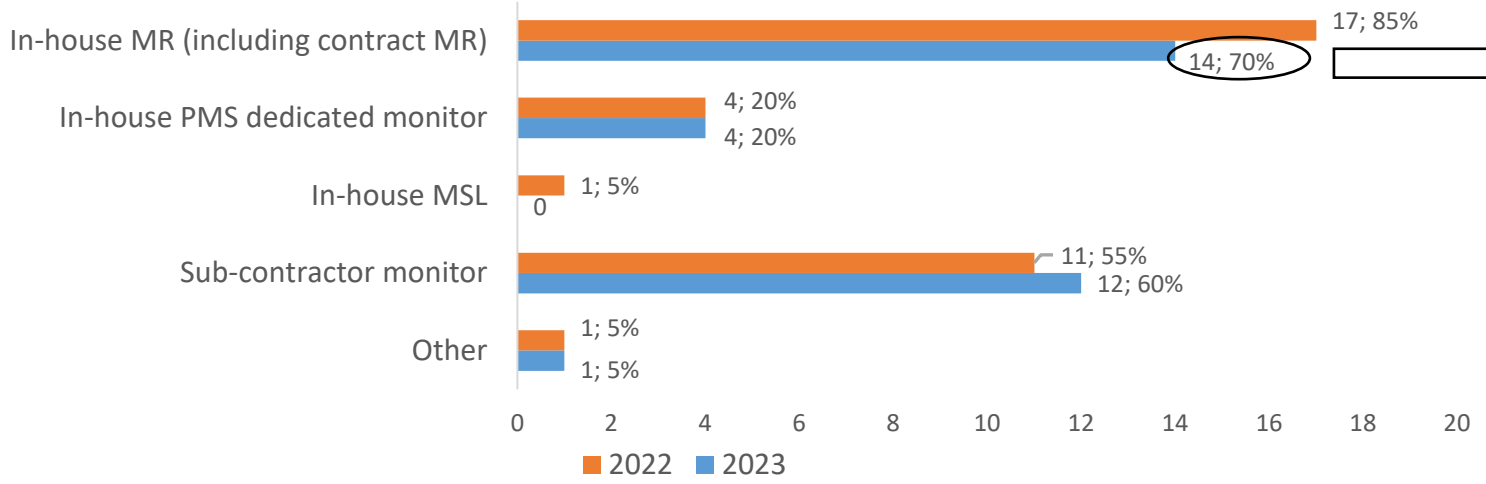
If "Yes", What is the main reason for the gap? (N=9)



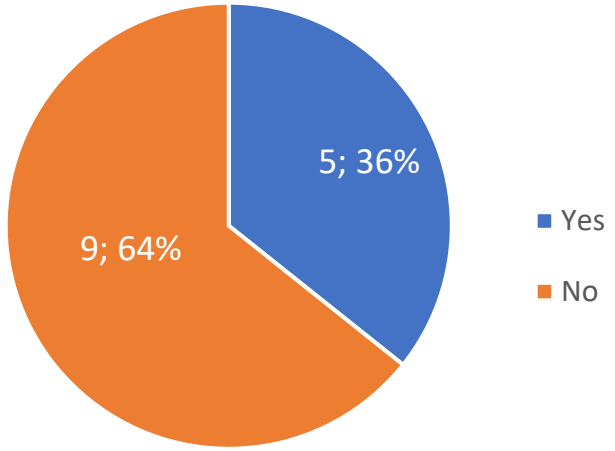
- 45% of companies had gap with initial assumptions regarding the DB survey. Main reasons were increase in resources, cost increase and others.

Organization for implementation

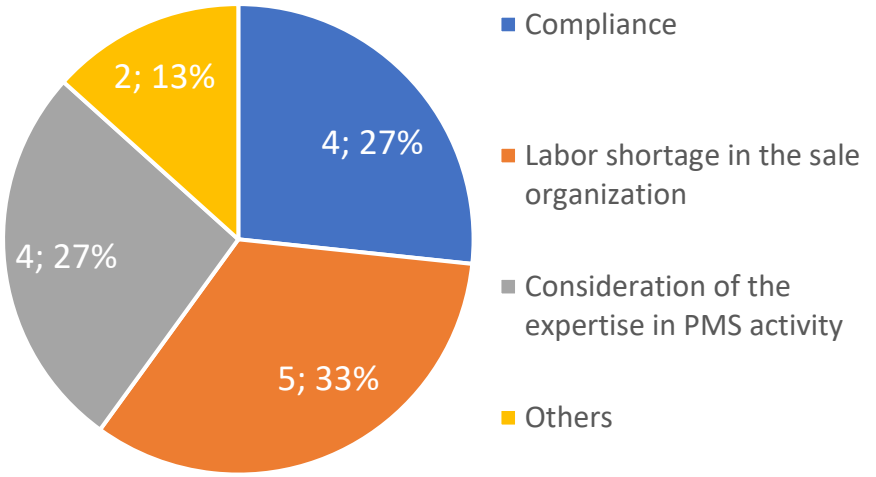
Person in charge of requesting registration and collecting CRF/re-questionnaire (Multiple answers allowed, N=20 on both 2022 and 2023)



If "In-house MR (including contract MR)" in 2023, the company plans to collect the CRF by a person in charge other than the in-house MR (including contract MR) in future (N=14)



Reason for not "In-house MR (including contract)" in 2023 (N=15)

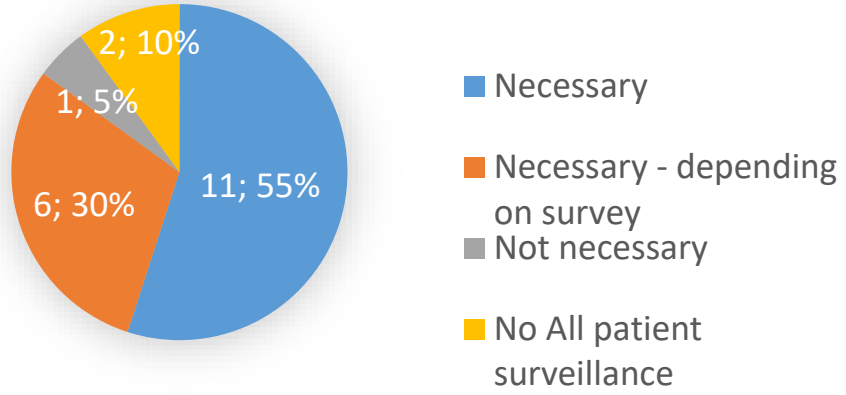


- In-house MR is in charge on 70% (14/20) in 2023, which is decreased from 85% (17/20) in 2022. Person in charge seems to be converting from "In-house MR" to "Non in-house MR", but more than half of the respondents still indicate that "In-house MR" is in charge of activities.
- Respondents less than half (36%; 5/14) considers the option other than "in-house MR" in future.
- No. 1 reason for not "in-house MR" is "labor shortage in the sales" (33%; 5/15), and "Compliance" and "Expertise in PMS" follows (both are 27%; 4/15).

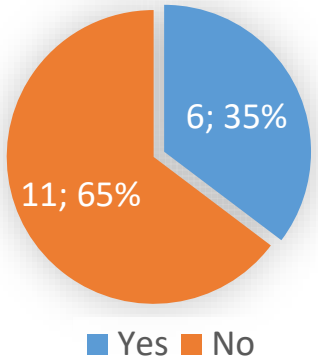
Informed Consent for All case surveillance

- ✓ All case surveillance are being conducted by 18 of 20 companies (90%)
- ✓ 17 out of 18 companies (94%) require informed consent from patients

Company policy requires informed consent from patient in all patient surveillance (N=20)

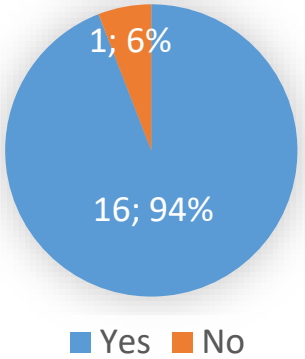


Participation in survey (N=17)



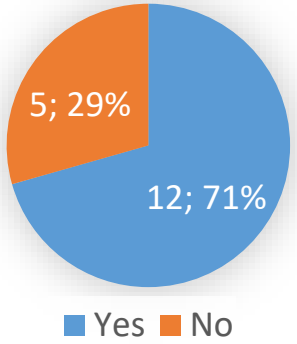
6 out of 17 companies (35%) require IC for participation in survey

Publication to congress/literature (N=17)



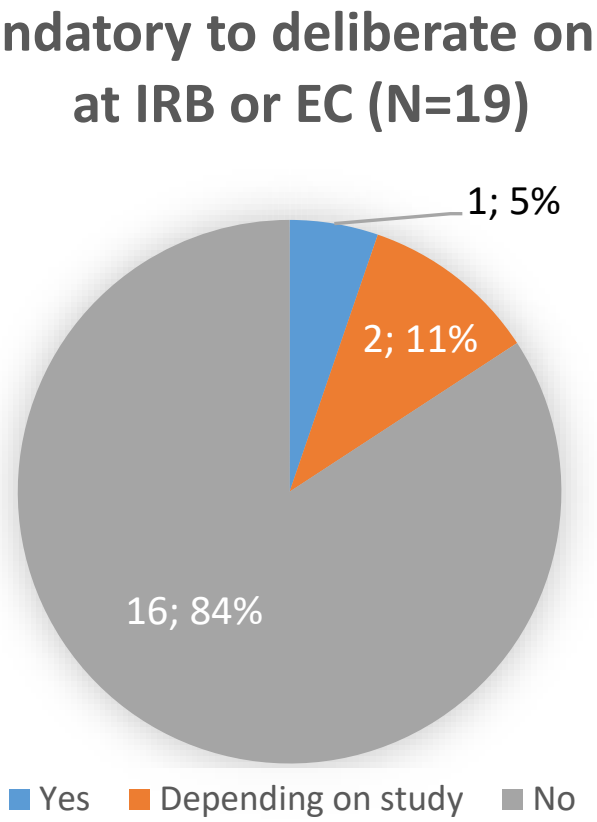
16 out of 17 companies (94%) require IC for publication to congress/literature

Secondary data use/providing data to 3rd party, overseas etc (N=17)



12 out of 17 companies (71%) require IC for secondary data use/providing data to 3rd party, overseas etc

Deliberation of Informed consent form at IRB/EC



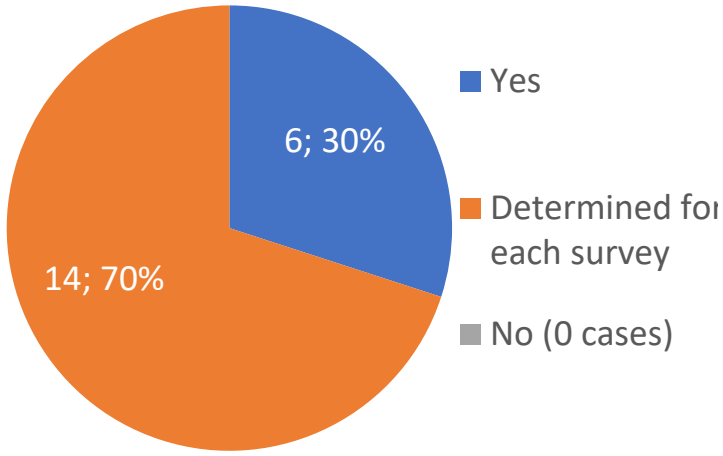
ICF: Informed Consent Form
IRB: Institutional Review Board
EC: Ethics Committee

Of 19 companies requiring consent to be obtained from patients

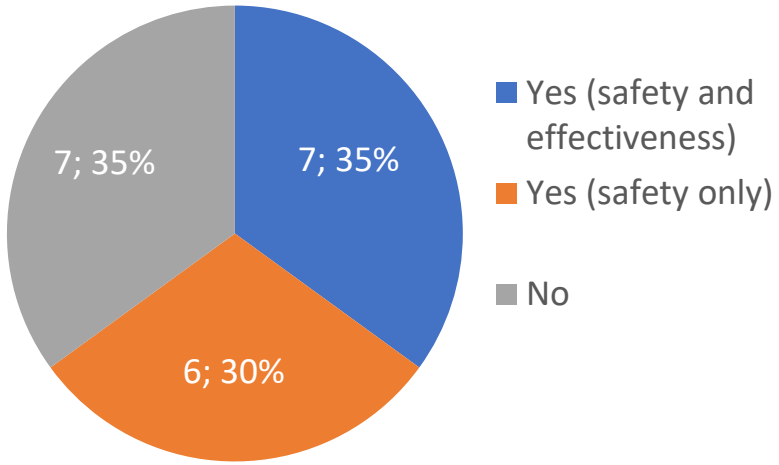
- 3 companies (16%) : ICF discussed by IRB or EC
- 16 companies (84%) : No discussion required

PMS Trend: Disclosure

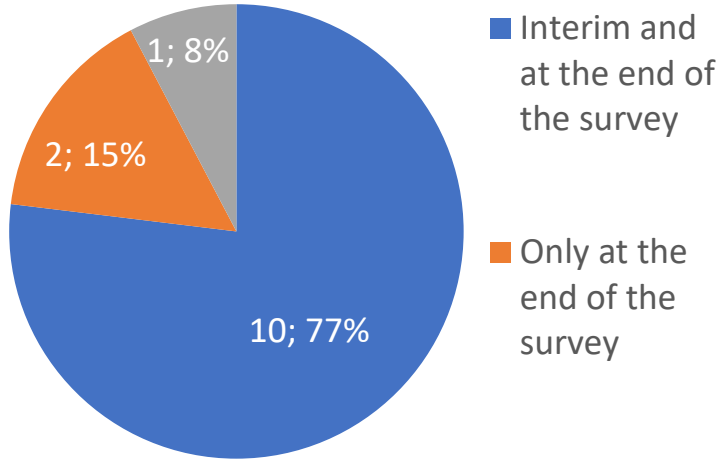
Have you presented PMS results at conferences, papers, etc.? (N=20)



Are the PMS results prepared in paper booklet or PDF (created by the PMS department)? (N=20)



If "Yes", in which timing PMS results distributed? (N=13)



- All companies published the PMS results at conferences, in papers, etc.
- Regarding the paper booklet and PDF (prepared by the PMS department), 85% of the companies also prepared interim reports. The data were published at an early stage without waiting for the survey to be completed, indicating the effective use of PMS data.