製薬協

TF8

CTDS Preparations: Pharmaceutical Company in Japan

Hisao Takeuchi, Sumitomo Dainippon, Katsuhiko Sawada, Taiho, Mina Izuchi, Pfizer, Shin Aoki, Astellas, Tomoko Kato, Sanofi, Wataru Ohtsuka, Chugai and Yoichi Higashibeppu, Eisai

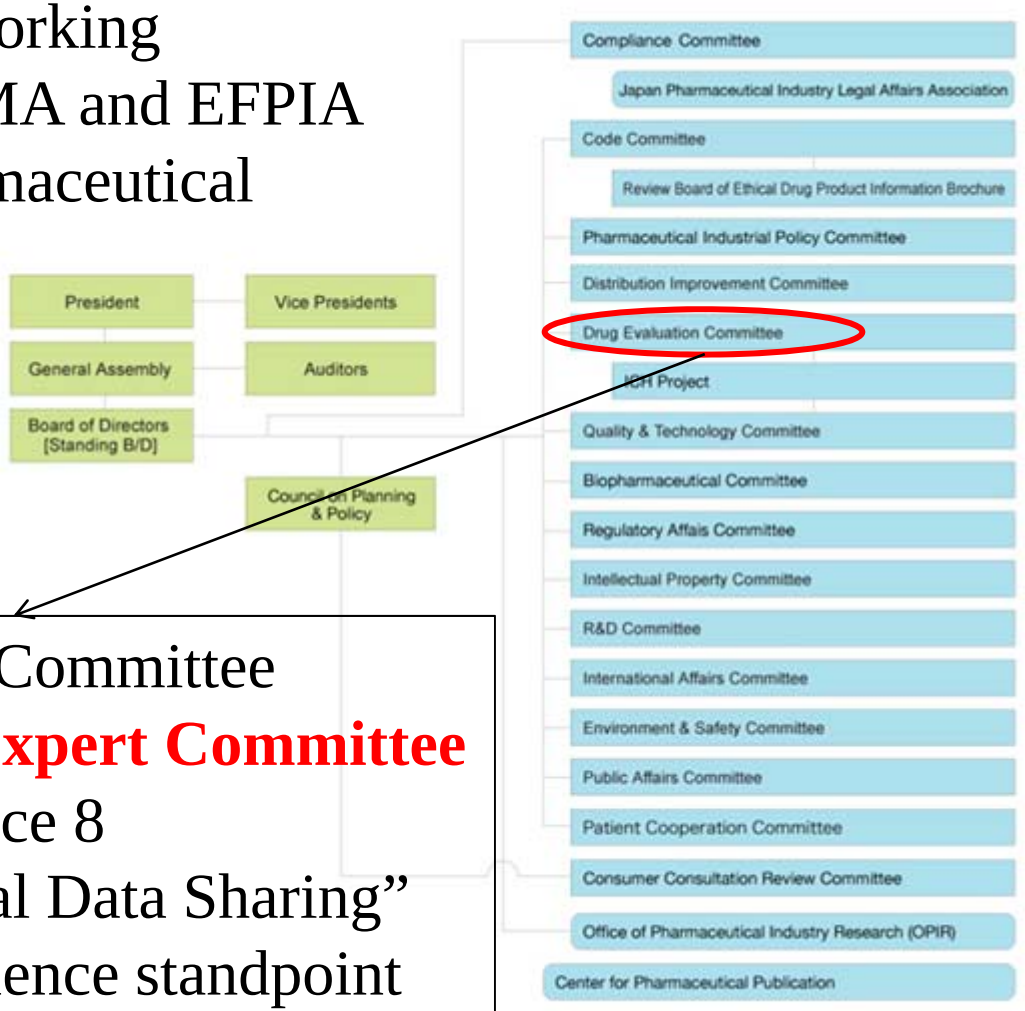
Disclaimer

The opinions in this presentation are those of the presenter and may not necessarily reflect the views of Company, PhUSE, or JPMA.

Who are we?

JPMA (Japan Pharmaceutical Manufacturers Association)

- Member of the IFPMA, working collaboratively with PhRMA and EFPIA
- 71 research-oriented pharmaceutical companies



We are a member of ....

One of the most Active Teams in JPMA

Drug Evaluation Committee

Data Science Expert Committee

TF8: Task Force 8

"Clinical Trial Data Sharing"

from a data science standpoint

Agenda of our Session

1. Summary of the questionnaire survey

Shin Aoki, Astellas

2. Challenge example in ”3. Sharing Results with Patients Who Participate in Clinical Trials”

Mina Izuchi, Pfizer

3. Multi-sponsor request website clinicalstudydatarequest.com

Yoichi Higashibeppu, Eisai

PhUSE Single Day Event
Tokyo, Japan
30 June 2015

CTDS Preparations: Pharmaceutical Company in JP

The results of the questionnaire

Shin Aoki
JPMA DS-TF8

Disclaimer

- This presentation shows the results of the questionnaire which were conducted by JPMA DS-TF8*. However the opinions expressed in this presentation are solely those of the presenter.
- JPMA DS-TF8 will officially publish the results in the future.

* Japan Pharmaceutical Manufacturers Association, Data Science Expert Committee, Task force 8

Principles for Responsible Clinical Trial Data Sharing*

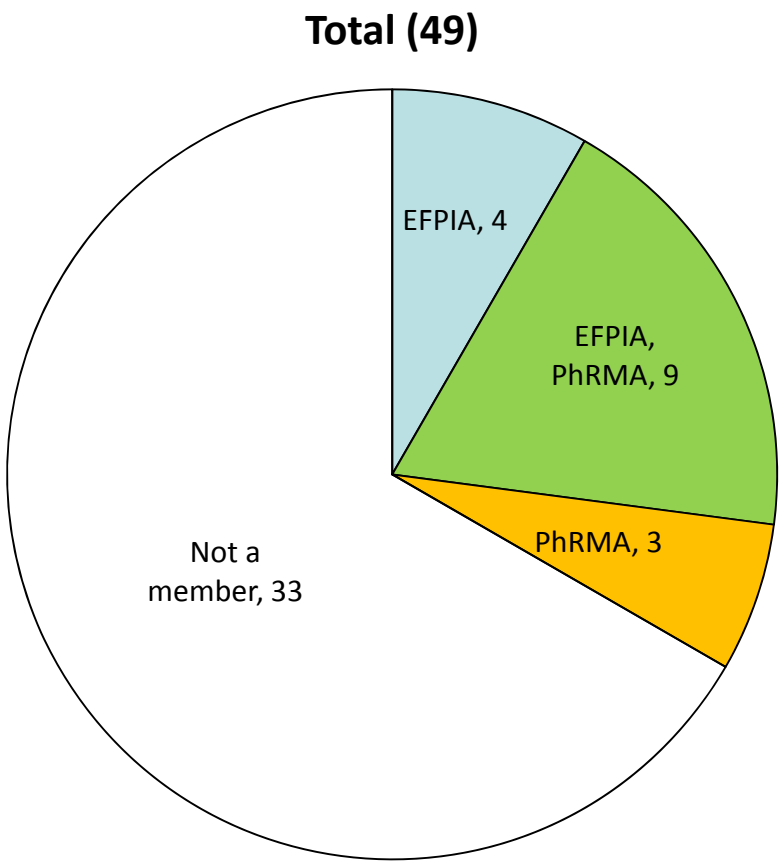
- **Principle 1**: Enhancing Data Sharing with Researchers
- **Principle 2**: Enhancing Public Access to Clinical Study Information
- **Principle 3**: Sharing Results with Patients Who Participate in Clinical Trials
- **Principle 4**: Certifying Procedures for Sharing Clinical Trial Information
- **Principle 5**: Reaffirming Commitments to Publish Clinical Trial Results

*責任ある臨床試験（治験）データ共有の原則 (EFPIA/PhRMA, 2013.07)
http://www.phrma-jp.org/archives/newsroom/release/nr2013/130731-1551.php

Questionnaire

- JPMA DS-TF8 prepared a questionnaire and carried out a survey. The objectives of the survey are:
  - To investigate how pharmaceutical companies in Japan apply to “Principles for Responsible Clinical Trial Data Sharing (EFPIA/PhRMA, 2013.07)”
  - To consider the result for the future activity as TF8.
- Period of survey: From 20 May 2015 to 29 May 2015
- Number of valid responses: 49/66

Is your company a member of EFPIA/PhRMA?



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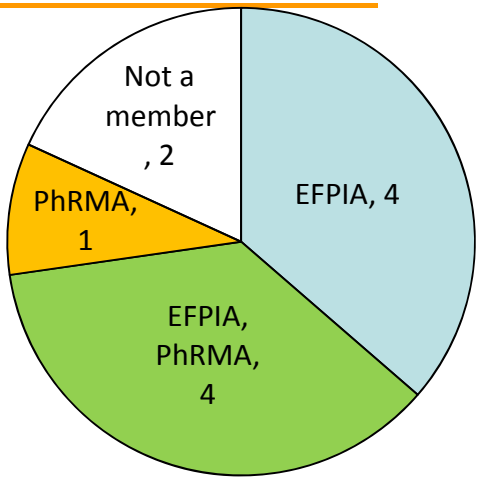

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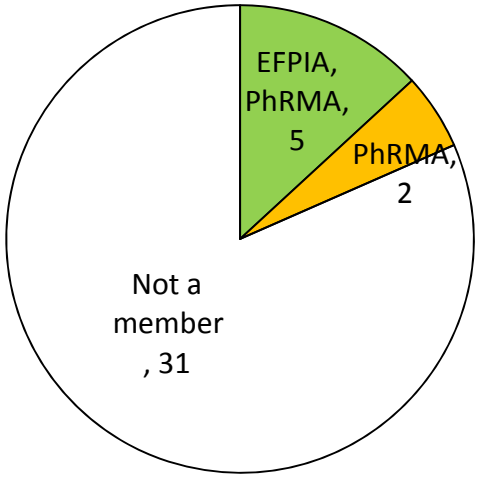
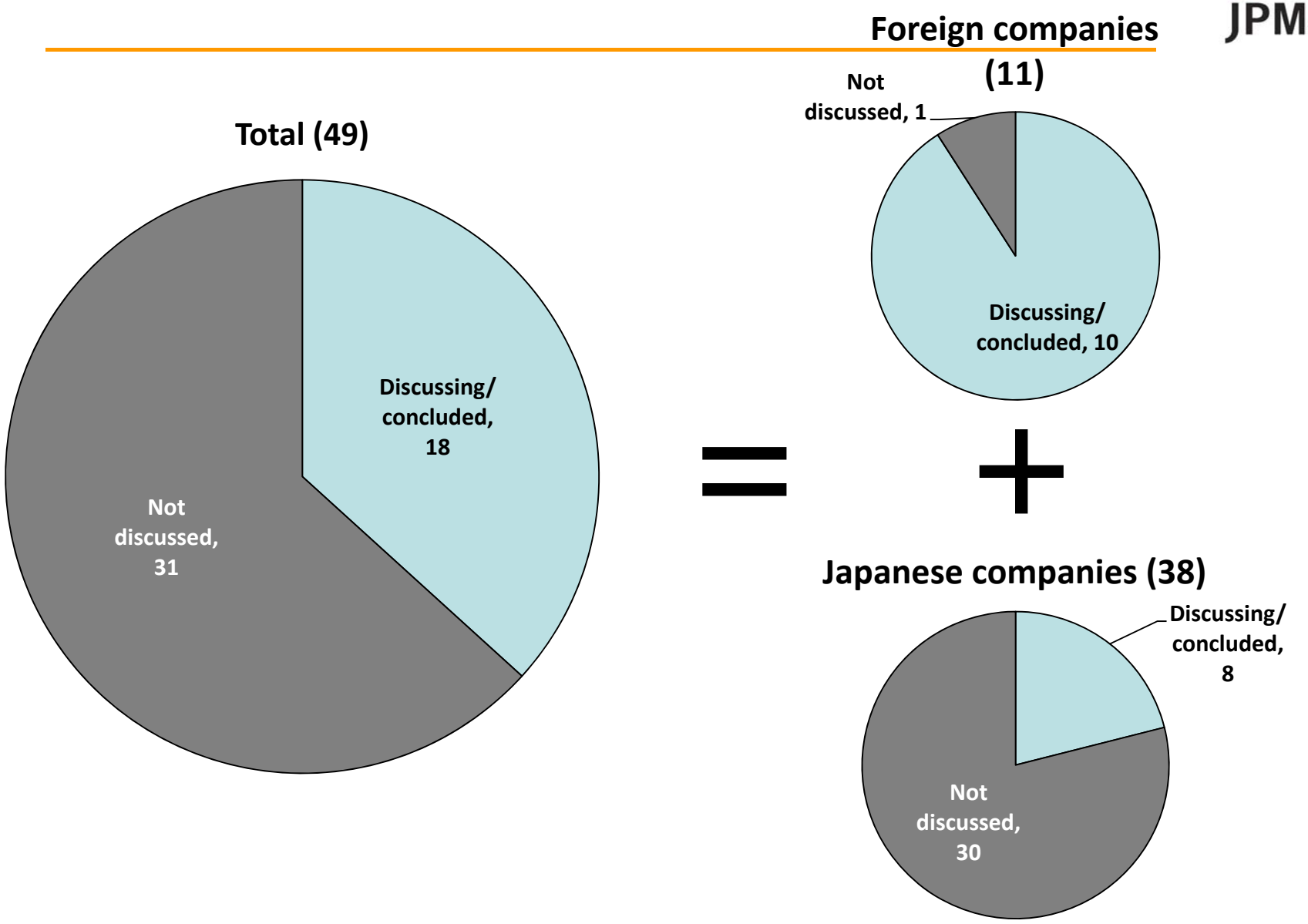
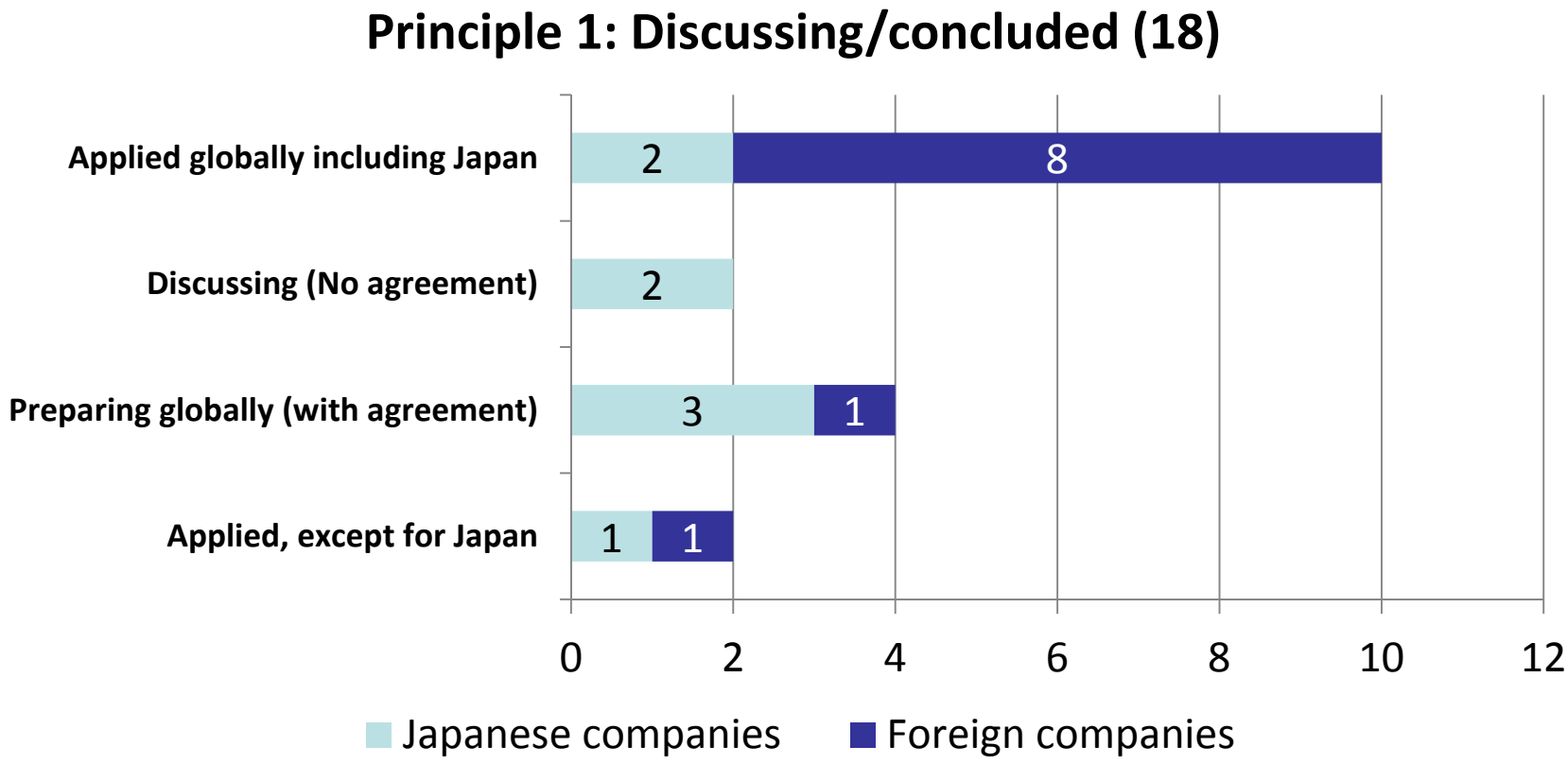


Discussion on Principle 1: Enhancing Data Sharing with Researchers



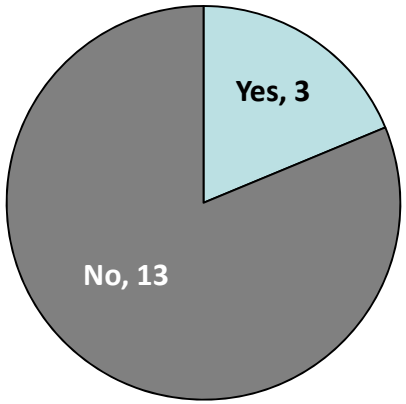
Principle 1: Enhancing Data Sharing with Researchers

Details of “Discussing/concluded” --- Current situation

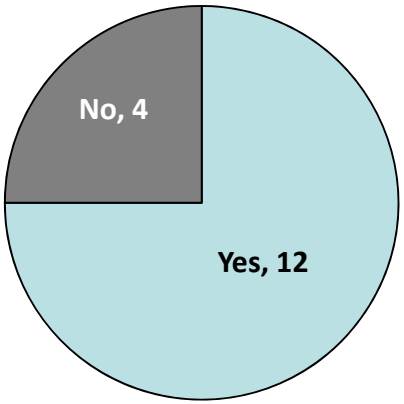


Principle 1: Enhancing Data Sharing with Researchers
Limitations in clinical studies

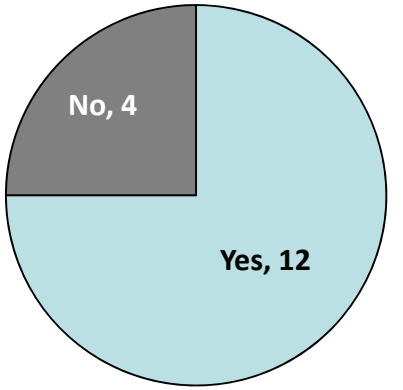
Limitation of Region (16)



Limitation of Study Completion Timing (16)

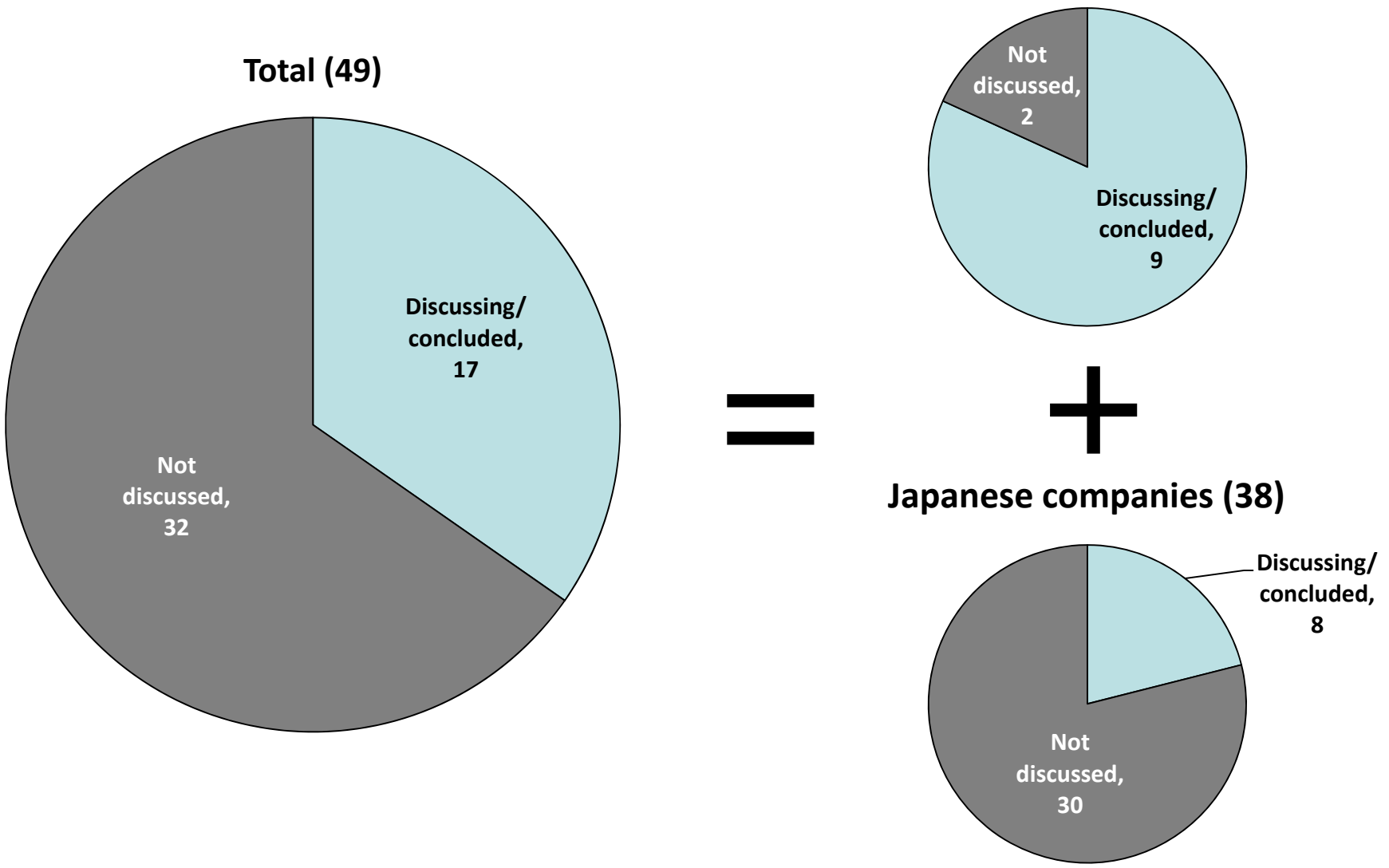


Limitation of Approval (16)



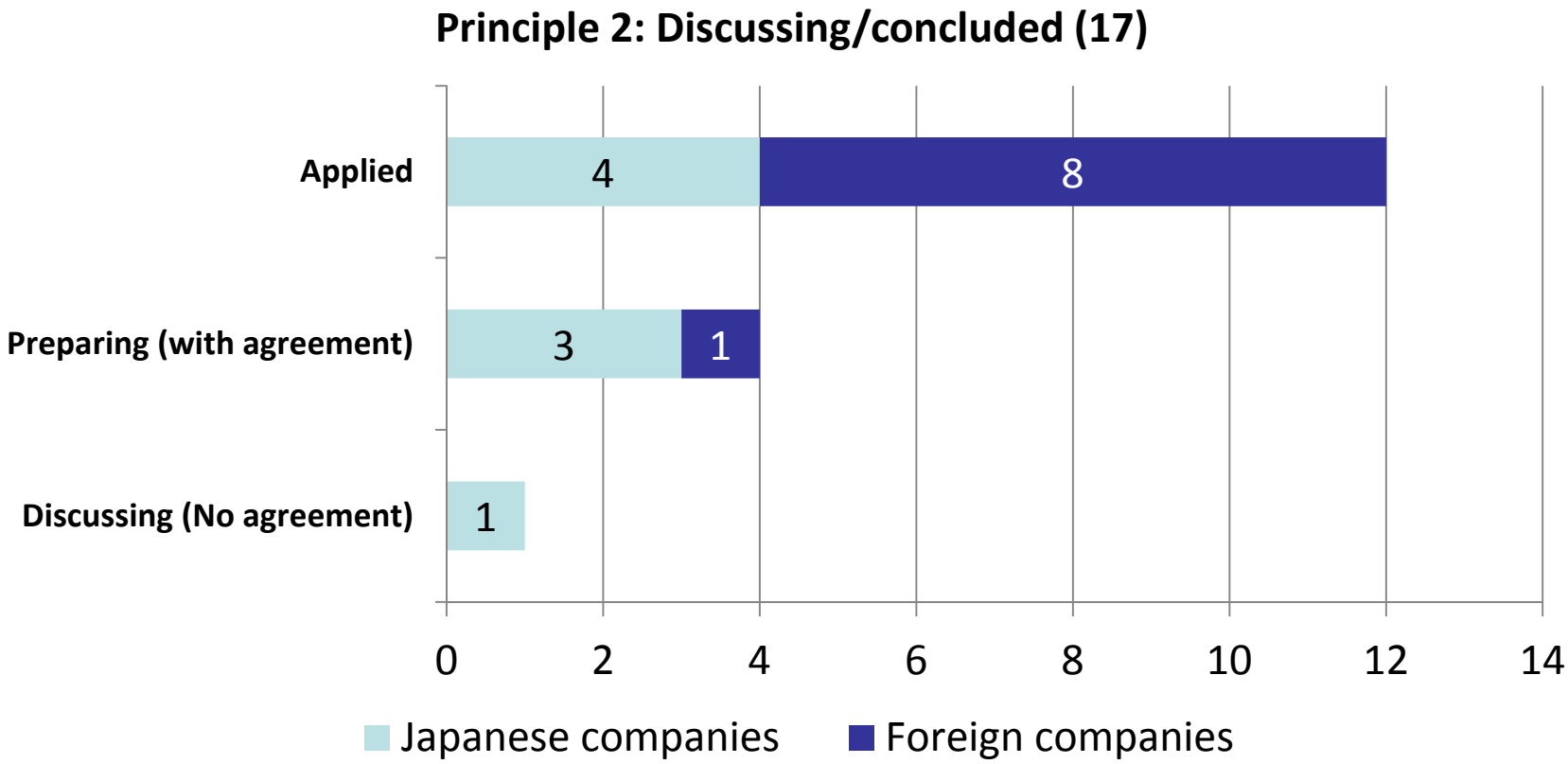
Except for “Discussing (No agreement)” from “Discussing/concluded” in principle 1

Discussion on Principle 2: Enhancing Public Access to Clinical Study Information

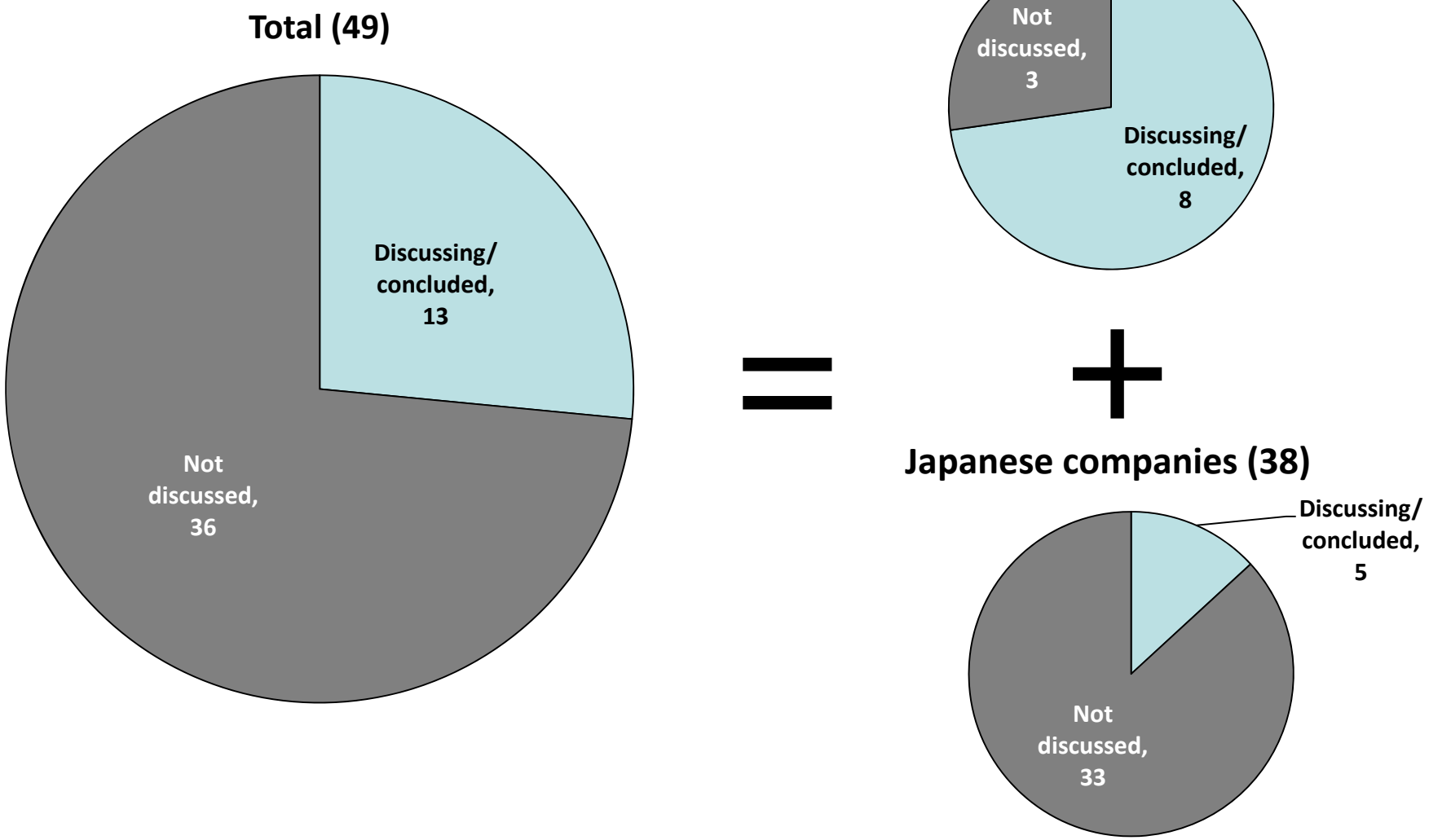


Principle 2: Enhancing Public Access to Clinical Study Information

Details of “Discussing/concluded” --- Current situation

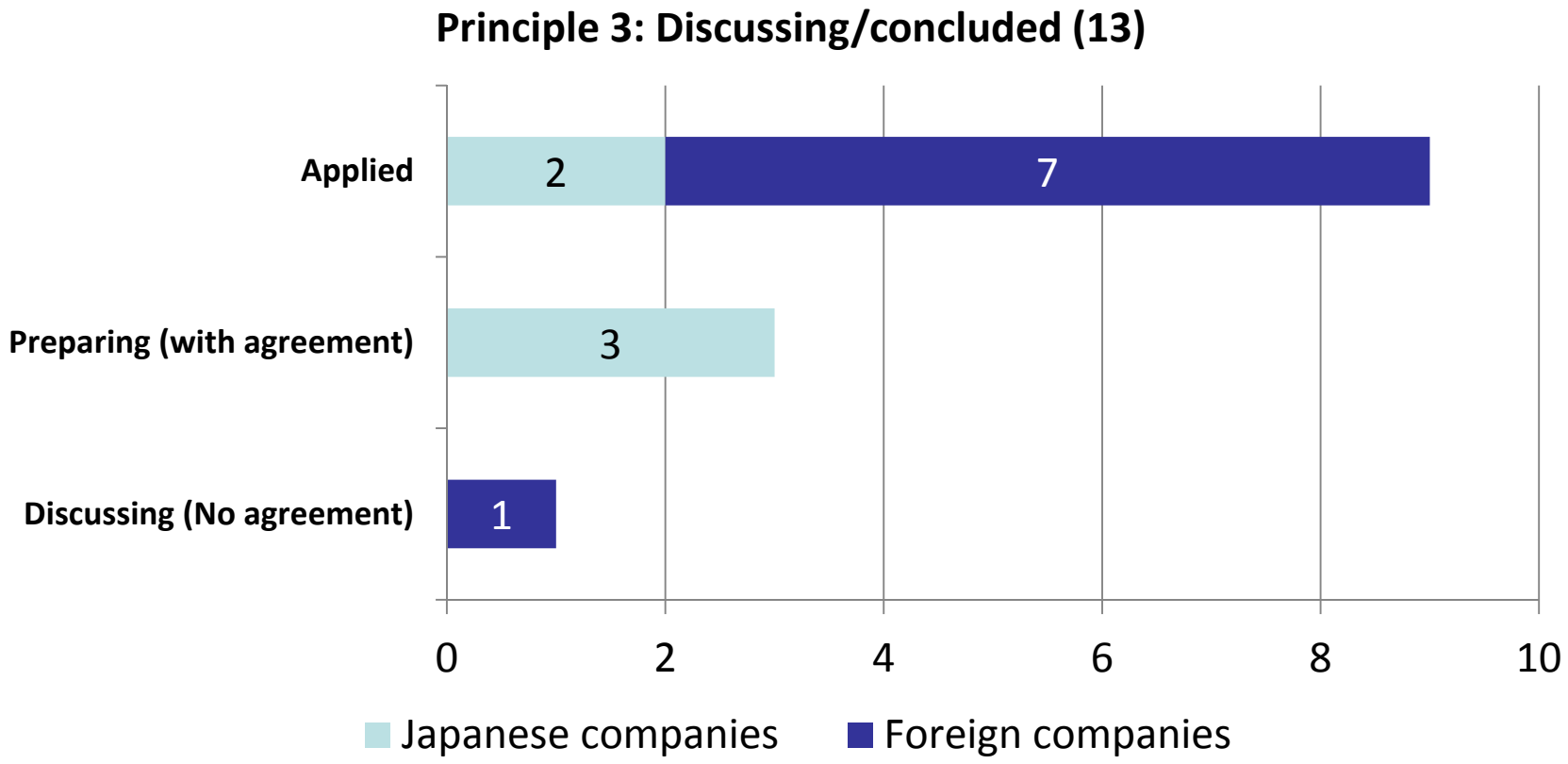


Discussion on Principle 3: Sharing Results with Patients Who Participate in Clinical Trials



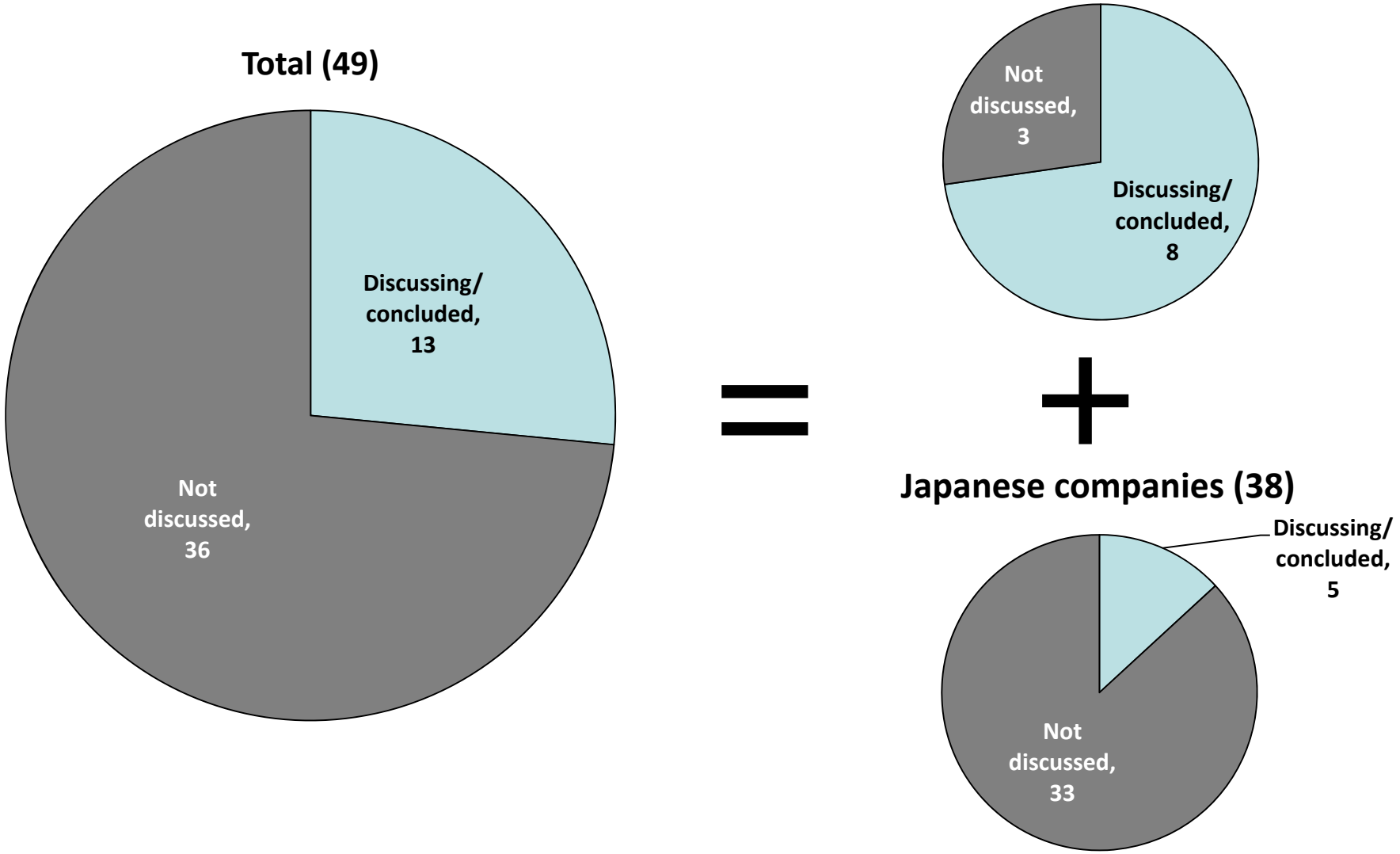
Principle 3: Sharing Results with Patients Who Participate in Clinical Trials

Details of “Discussing/concluded” --- Current situation



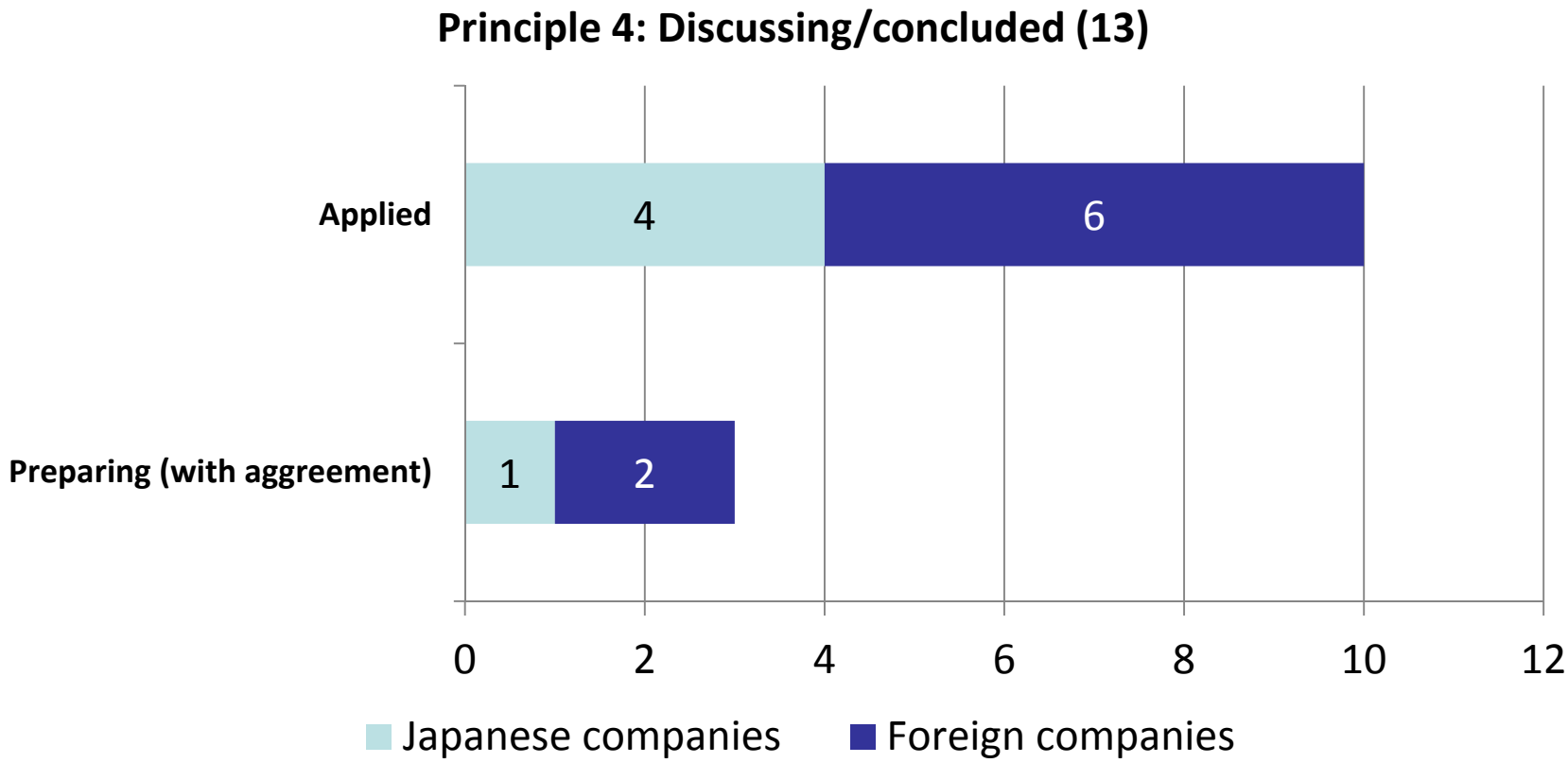
Discussion on Principle 4: Certifying Procedures for Sharing Clinical Trial Information

JPMA



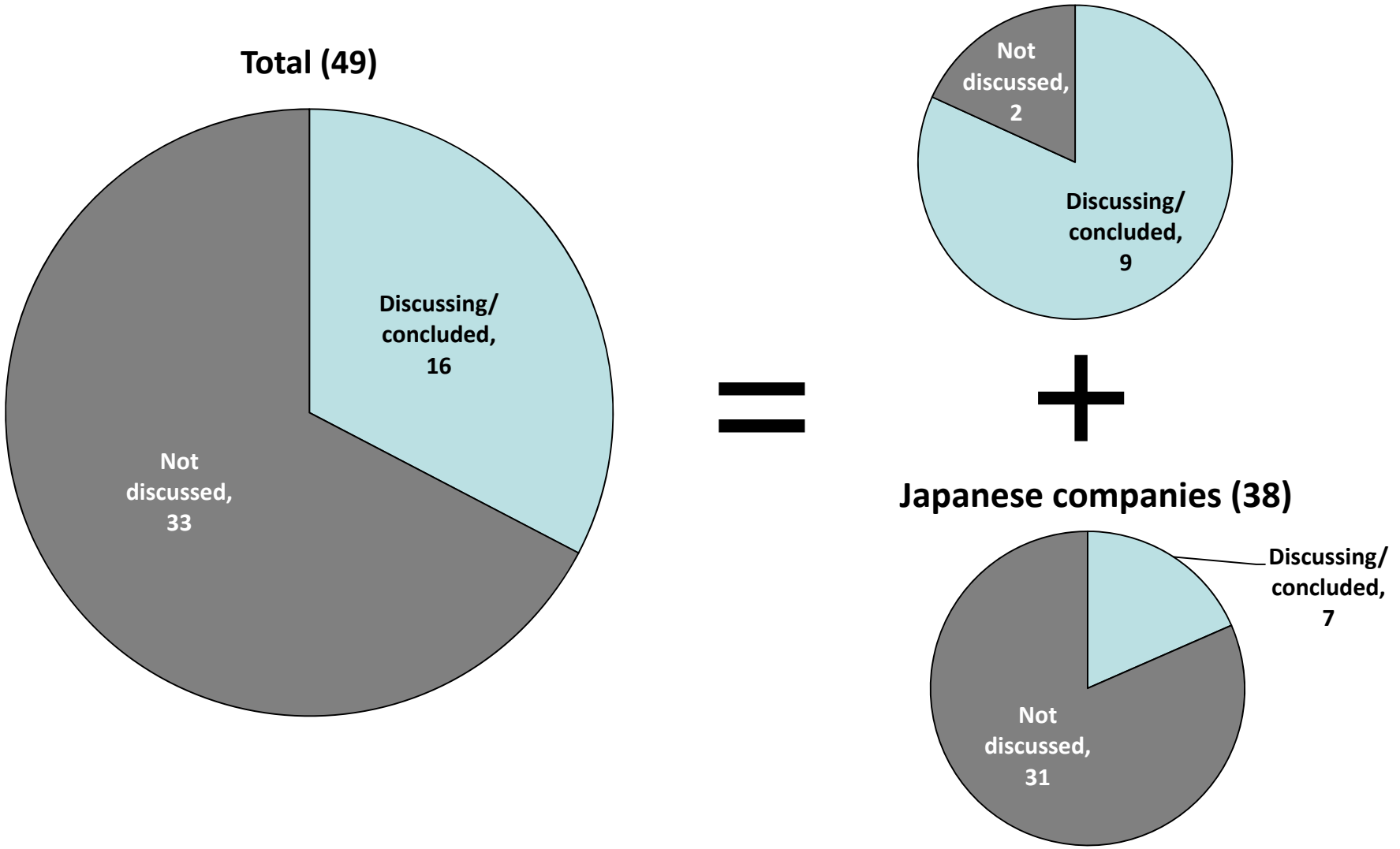
Principle 4: Certifying Procedures for Sharing Clinical Trial Information

Details of “Discussing/concluded” --- Current situation



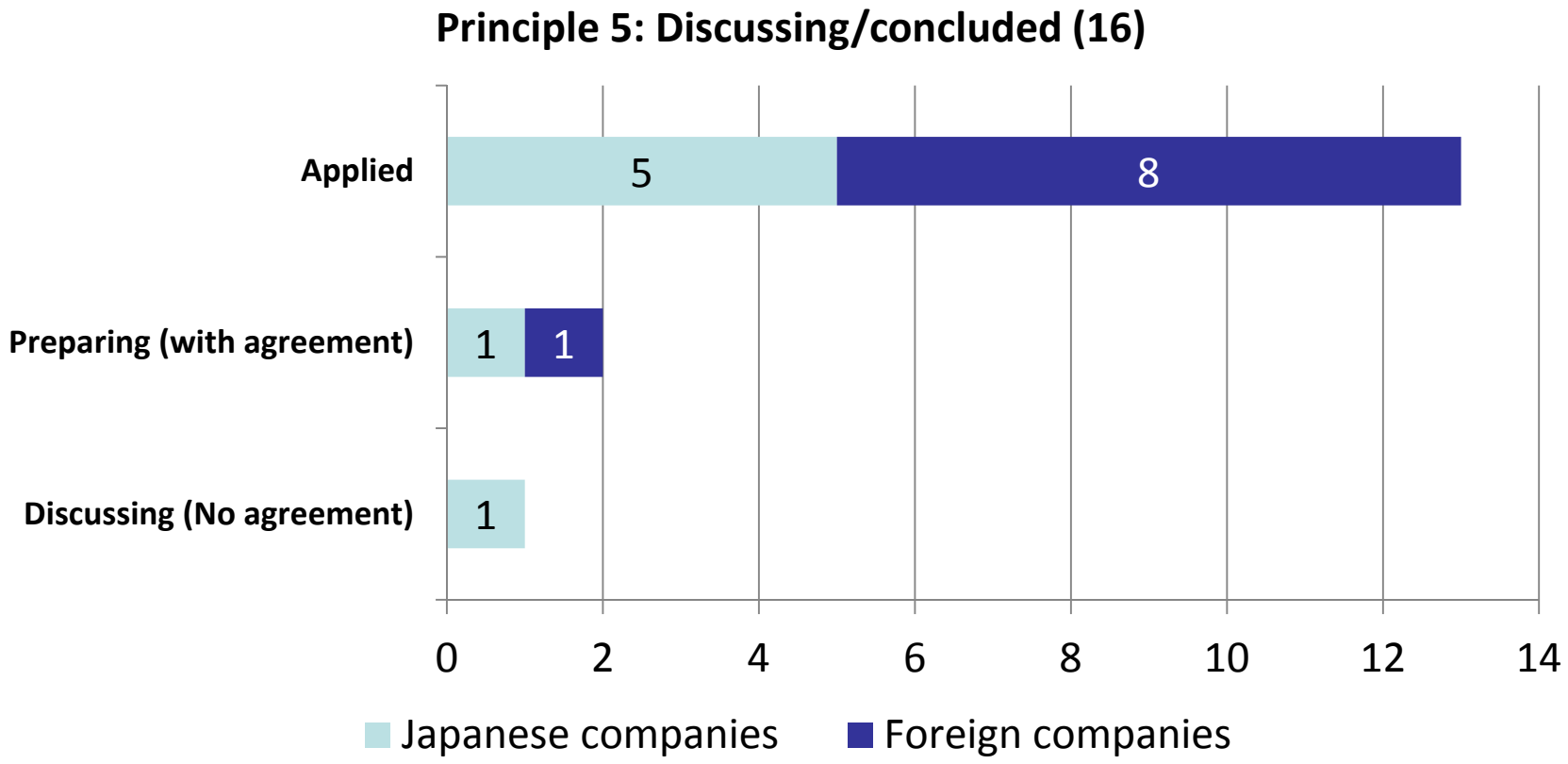
Discussion on Principle 5: Reaffirming Commitments to Publish Clinical Trial Results

JPMA



Principle 5: Reaffirming Commitments to Publish Clinical Trial Results

Details of “Discussing/concluded” --- Current Situation



Difference in awareness/approach between overseas and Japan:

F	Principles 1, 2, 3, 4 and 5: Japan has not started any actions regarding each principle. We recognize the necessity of actions, but have not reached the agreement.
F	In principle, Head office responds.
F	Awareness and approach are weaker in Japan compared with overseas.
F	Principles 3 and 4: Data to be shared, different language per region, different policies and regulations depending on a country.
J	Principle 1: Japan office tends to make a rule at first, so discussion with overseas comes after the rule making.
J	Principle 1: Japan is under discussion. Principle 2: Japan is applying now. Principle 3: Japan has not kicked off yet.
J	Principle 2
J	At this point, difference is not clear because Japan and overseas have not discussed together.
J	Principle 3

J: Japanese company, F: Foreign company

Remarks

- Foreign companies are more likely to apply to each principle than Japanese companies.
- All EFPIA companies apply to principles (except for one company in principle 3&4).
- Discussing/concluded in Principle 3&4 is lower than that in other principles.

JPMA

Details of Limitation of Region (Yes):

J	Exclusion of studies whose data and CSR are not English
J	Under discussion
J	Studies sponsored by EU/US

Details of Limitation of Study Completion Timing (Yes):

F	Studies which have been approved in EU/US after 1 Jan 2014 (In case of additional indications, studies for such additional indications only)
F	Please see “clinical data sharing” page in our company’s website.
F	Studies whose NDA submissions were made after January 2014
F	Studies after 2006
F	Studies which have been started after 2005 (TBD)
F	Studies after 1 Jan 2014
F	Studies which have been completed after Sep 2007 (but on a case-by-case basis)
J	(Current situation) Studies which have been completed before 10 years of clinical study data disclosure/provision requests
J	Under discussion
J	Studies which have been completed after Jan 2010
J	Studies which have been approved in EU/US after Jan 2014 and included in the Dossier

J: Japanese company, F: Foreign company

JPMA

Details of Limitation of approval (Yes):

F	Only approved indications
F	Only approved drugs in EU/US (For a vaccines, an approval in either EU or US is OK. For a non-vaccine, approvals both in EU and US are necessary.)
F	Only approved drugs in EU/US
F	Please see “clinical data sharing” page in our company’s website.
F	Only approved drugs (or drugs whose developments were terminated)
F	Only studies which were submitted to the authorities (EMA, FDA, etc.), studies under the review at the authorities, and studies which will be submitted to the authorities
F	Studies of projects which have been approved in EU/US or whose developments were terminated, and studies which have passed 2 years from the study completion (but on a case-by-case basis)
F	Data on studies (excluding reference studies) whose reviews were completed by authorities in JP/US/EU are disclosed after the approvals
J	Studies which have been approved in any country after 2005
J	Under discussion
J	Only approved drugs in US/EU
J	Studies which have been approved in EU/US after Jan 2014 and included in the Dossier

J: Japanese company, F: Foreign company

Clinical Trial Result Disclosure

PhUSE Single Day Event

30 June 2015

Mina Izuchi
Medical Writing
Pfizer Japan Inc.

Disclaimer

All the views expressed in this presentation are personal opinions and do not convey any institutional view.

Agenda

- New Statement form of PhRMA / EFPIA
- Three themes from PhRMA / EFPIA Principles
- Status in Pfizer / Pfizer Japan
- Conclusion

New Statement form PhRMA / EFPIA

Principles for Responsible Clinical Trial Data Sharing

Our Commitment to Patients and Researchers

Biopharmaceutical companies are committed to enhancing public health through responsible sharing of clinical trial data in a manner that is consistent with the following Principles:

- **Safeguarding the privacy of patients**
- **Respecting the integrity of national regulatory systems**
- **Maintaining incentives for investment in biomedical research**

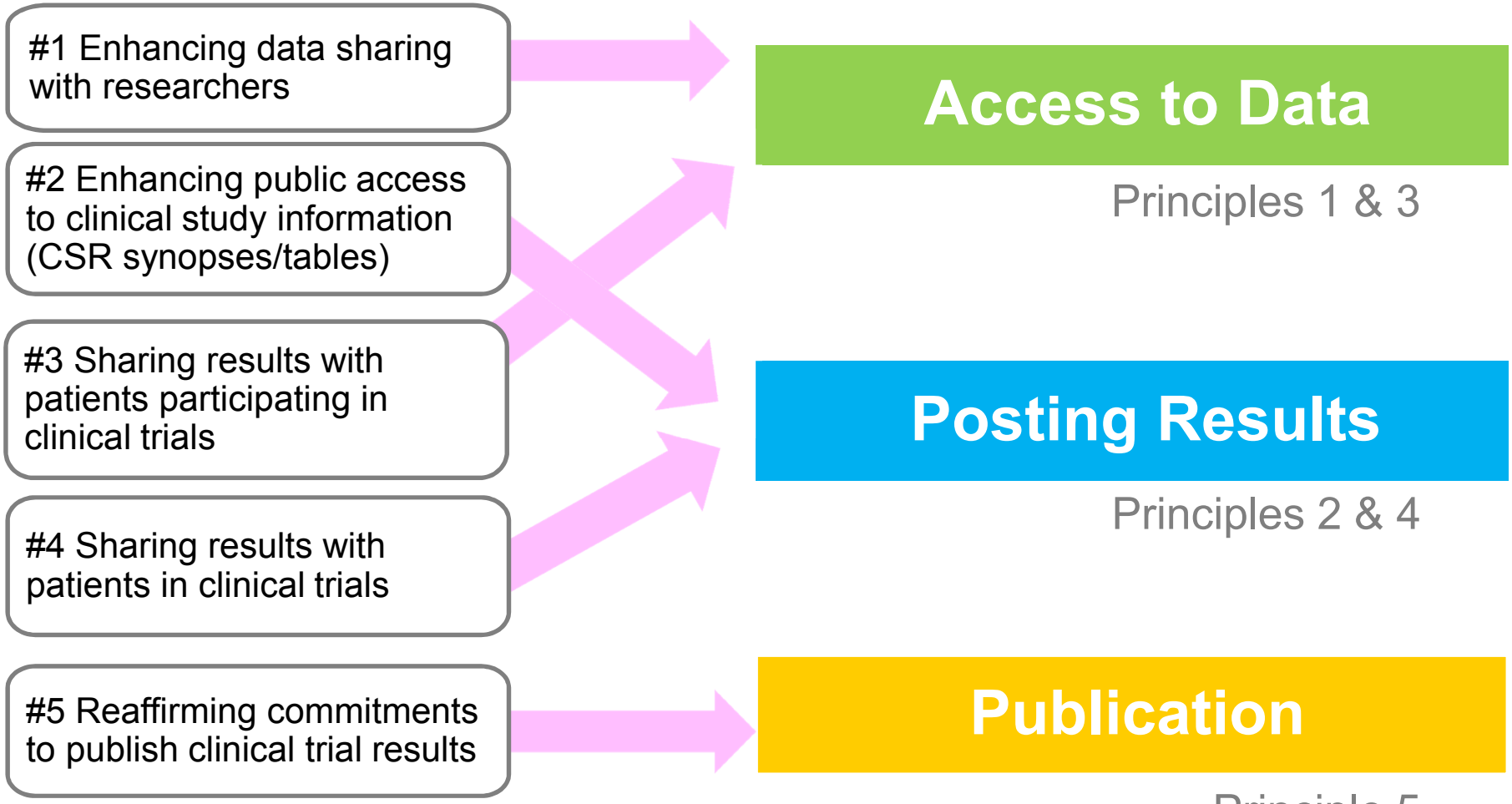
⇨ Link

"Principles for Responsible Data Sharing" issued by PhRMA and EFPIA in July 2013.

Three Themes from PhRMA / EFPIA Principles

< 5 Principles >

< 3 Themes >



Status in Pfizer and Pfizer Japan

1. Enhancing data sharing with researchers
   - Biopharma-company needs to establish review board.

INSPIIRE

2. Enhancing public access to clinical study information
   - Public Disclosure Synopsis (PDS) for studies which submitted to FDA, EMA or national competent authority of EU

Pfizer.com, Eudra, JAPIC

3. Sharing results with patients in clinical trials
   - Providing a factual result summary to patients

Pfizer Link, Blue button

4. Certifying procedures for sharing clinical trial information
   - Certifying a publicly available web site

Pfizer.com

5. Reaffirming commitments to publish clinical trial results
   - Publication of all P3 studies' results (at minimum)

SOP

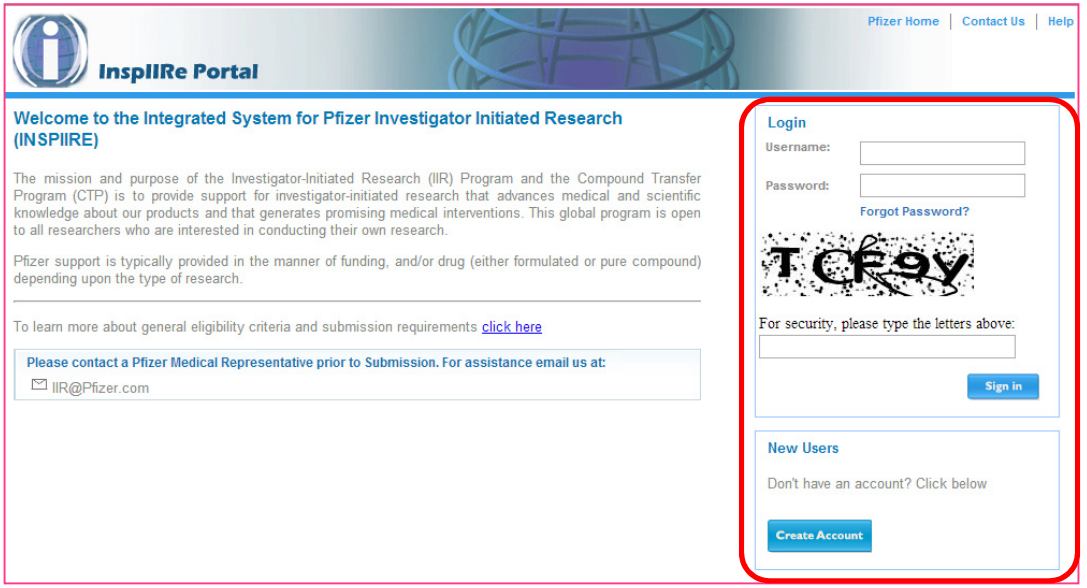
INSPIIRE

Principle #1
Community Enhancing data sharing with researchers

INSPIIR:
Process for patient-level data requests in Pfizer

Researchers submit request through INSPIIRE Portal

INSPIIRE Portal



Pfizer Internal Review

Pfizer Review Committee

Decision

Decline

Submit Proposal for Independent Review

Decline

Pfizer notifies researcher & posts outcome

Approve

Approve

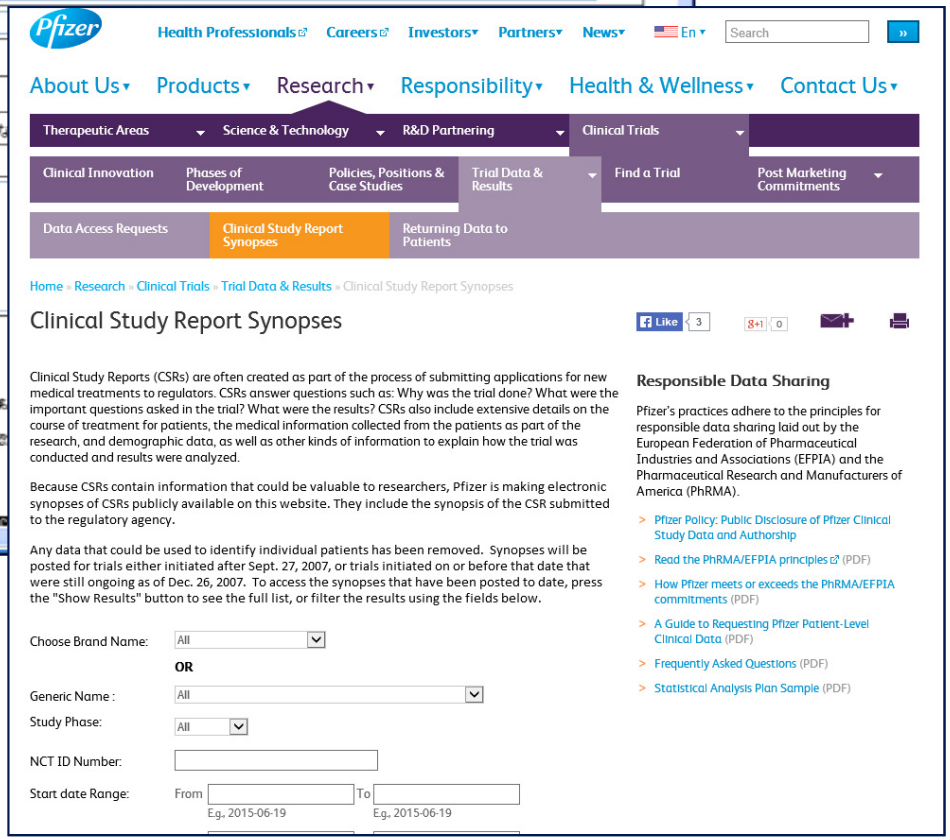
Independent Review Panel

Agreement and Access

Pfizer.com / Eudra / JAPIC

Principle #2
Enhanced results posting
(CSR synopses / tables)

Pfizer.com / Eudra / JAPIC: Enhancing public access to clinical study information



Pfizer Link

Principle #3
Clinical Trial Alumni Community

Pfizer Link: Clinical Trial Alumni Community in Pfizer

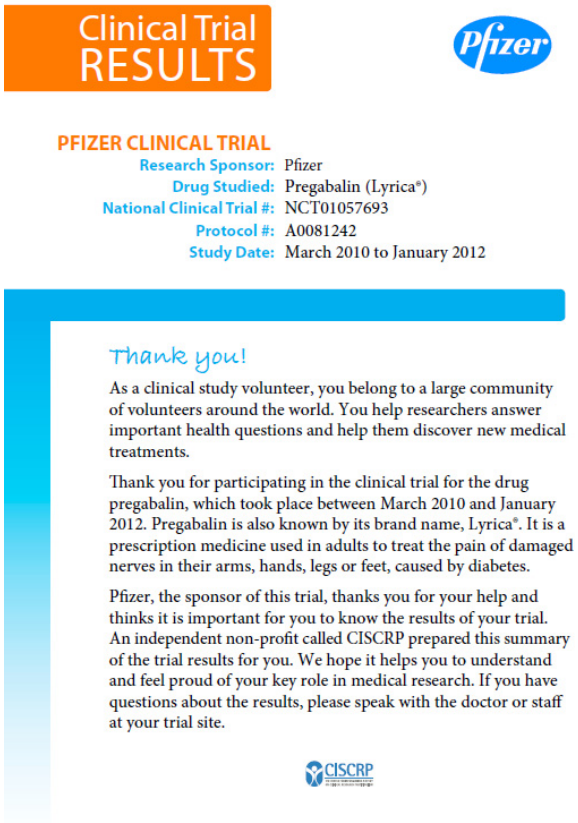
- Maintain connection with patients who have recently completed Pfizer studies
- Patient opt-out as a default, but require registration to activate
- Share study results
- Engage for future studies, REMS commitments, etc.
- Patient KOLs
- Research Ambassadors (capture stories to video)
- Positioned to be the vehicle for sharing results
- In Production. In partnership with Alliance Partners, in 2014, 92 U.S. studies/~2500 patients receiving enrollment packets. Fully integrated into the study close-out process.

Clinical Trial Patient Lay Summaries

Principle #3

Sharing results with patients

Patient Lay Summaries: Distribution Program Overview in US



Clinical Trial RESULTS

PFIZER CLINICAL TRIAL

Research Sponsor: Pfizer
Drug Studied: Pregabalin (Lyrica®)
National Clinical Trial #: NCT01057693
Protocol #: A0081242
Study Date: March 2010 to January 2012

Thank you!

As a clinical study volunteer, you belong to a large community of volunteers around the world. You help researchers answer important health questions and help them discover new medical treatments.

Thank you for participating in the clinical trial for the drug pregabalin, which took place between March 2010 and January 2012. Pregabalin is also known by its brand name, Lyrica®. It is a prescription medicine used in adults to treat the pain of damaged nerves in their arms, hands, legs or feet, caused by diabetes.

Pfizer, the sponsor of this trial, thanks you for your help and thinks it is important for you to know the results of your trial. An independent non-profit called CISCRP prepared this summary of the trial results for you. We hope it helps you to understand and feel proud of your key role in medical research. If you have questions about the results, please speak with the doctor or staff at your trial site.

CISCRP

- Patients study should post ClinicalTrials.gov after launch
- After trial results are posted on ClinicalTrials.gov, a neutral 3rd party partner will translate the results into lay language
  - Summaries validated at 6th-8th grade reading level for broad comprehension
  - Summaries can be created in print, audio, and webpage formats to meet the preference of study volunteers
- Lay language translations will be reviewed by Pfizer for accuracy and approvals
- The 3rd party will engage study sites to distribute lay results via mail or “Pfizer Link” to patients

Press release for Pfizer Japan (1)
Nikkan yakugyo of 5 March 2015

企業／団体. 02

内資よベンチャーたれ、ファイザーがパートナーに 原田・医薬開発部門長（日刊）

ファイザーの原田明久取締役執行役員・医薬開発部門長は4日の会見で、日本のアカデミアに埋もれている創薬シーズを新薬として開発するために、国内で事業展開している中小製薬企業が創薬ベンチャーの役割を果たすべきではないかと主張した。その上で「もし国内企業がリスクを取りづらいと考えているのなら、ファイザーがパートナーになり、一緒にリスクを取りにいくことも考えていきたい」と述べた。

海外では、アカデミアの研究から出てきた創薬シーズを実用化し、POC取得までこぎ着ける役割をバイオベンチャーが担っている。しかし、日本のバイオベンチャーは規模が小さく、数億円単位の研究開発費を工面するのにも苦戦している状況だ。

Clinical Trial
Patient Lay Summaries

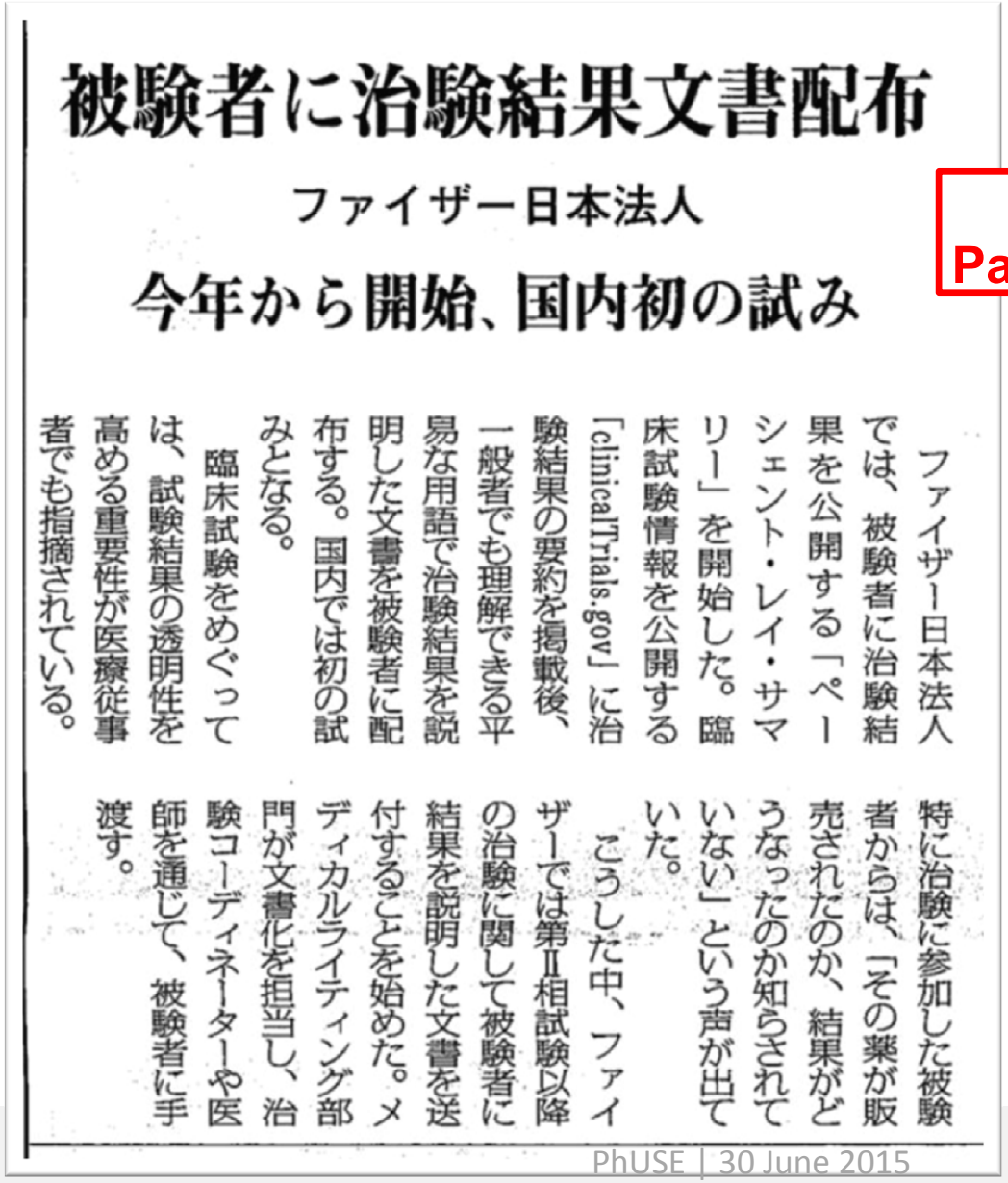
日本には創薬経験があり、治験薬の製造能力も持ベンチャーの役割を果たせば、日本の創薬環境は「国内企業はリスクを取りたがらないところがあ[illegible]ートナーになることもできるかもしれない。一緒にリスクを取ることを今後、考えていきたい」と述べた。

●患者向け治験結果説明書の作成へ

また原田氏は、医学の専門知識がない患者にも治験結果が分かるよう、平易な言葉に直した文書を作成し、被験者に配布するプログラムを始めることを明らかにした。ファイザーのメディカルライティング部門担当者が患者向け文書を作成し、専門医の監修を踏まえて正確性を担保した上で、治験終了後、被験者に結果を送る。こうした取り組みは国内で初めてだという。

また医薬品リスク管理計画の概要や、医薬品リスク管理計画・製造販売後基本計画書も自社ホームページ上で公表し始めた。医薬品の安全対策を、製薬企業と規制当局間のやり取りだけに使うのではなく、積極的に情報公開して透明性を高めたい考えだ。

Press release for Pfizer Japan (2)
Yakuji nippo of 18 March 2015



被験者に治験結果文書配布

ファイザー日本法人

今年から開始、国内初の試み

ファイザー日本法人では、被験者に治験結果を公開する「ペーシェント・レイ・サマリー」を開始した。臨床試験情報を公開する「clinicalTrials.gov」に治験結果の要約を掲載後、一般者でも理解できる平易な用語で治験結果を説明した文書を被験者に配布する。国内では初の試みとなる。

臨床試験をめぐっては、試験結果の透明性を高める重要性が医療従事者でも指摘されている。特に治験に参加した被験者からは、「その薬が販売されたのか、結果がどうなったのか知らされていない」という声が出ていた。

こうした中、ファイザーでは第Ⅱ相試験以降の治験に関して被験者に結果を説明した文書を送付することを始めた。メディカルライティング部門が文書化を担当し、治験コーディネーターや医師を通じて、被験者に手渡す。

Clinical Trial Patient Lay Summaries

Blue Button

Principle #3
Returning Clinical Trial Data to Patients

Blue Button® : Returning Patient Clinical Data in Pfizer

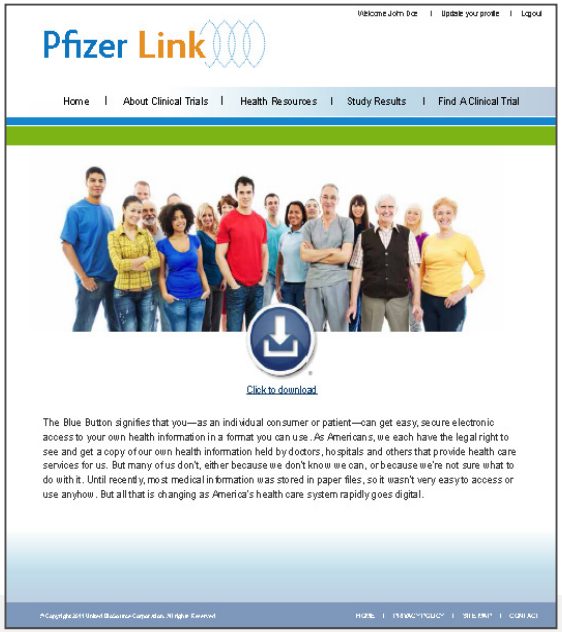
Blue Button Overview

- White House Initiative launched August 2010
- Standardized technology that would allow Veteran's to easily access & download their personal health information to create empowered patients
- VA's "Blue Button" made available for national use by any group in 2011

Source: http://www.va.gov/bluebutton/

1st Pharma to Launch Blue Button Pilot Giving Patients in our Studies their Electronic Clinical Data

- Patients access Blue Button through Pfizer Link (online community for patients completing Pfizer studies)
- Individualized electronic data provided in XML and PDF format
- Complies with HIPAA, Safe Harbor & Patient Privacy



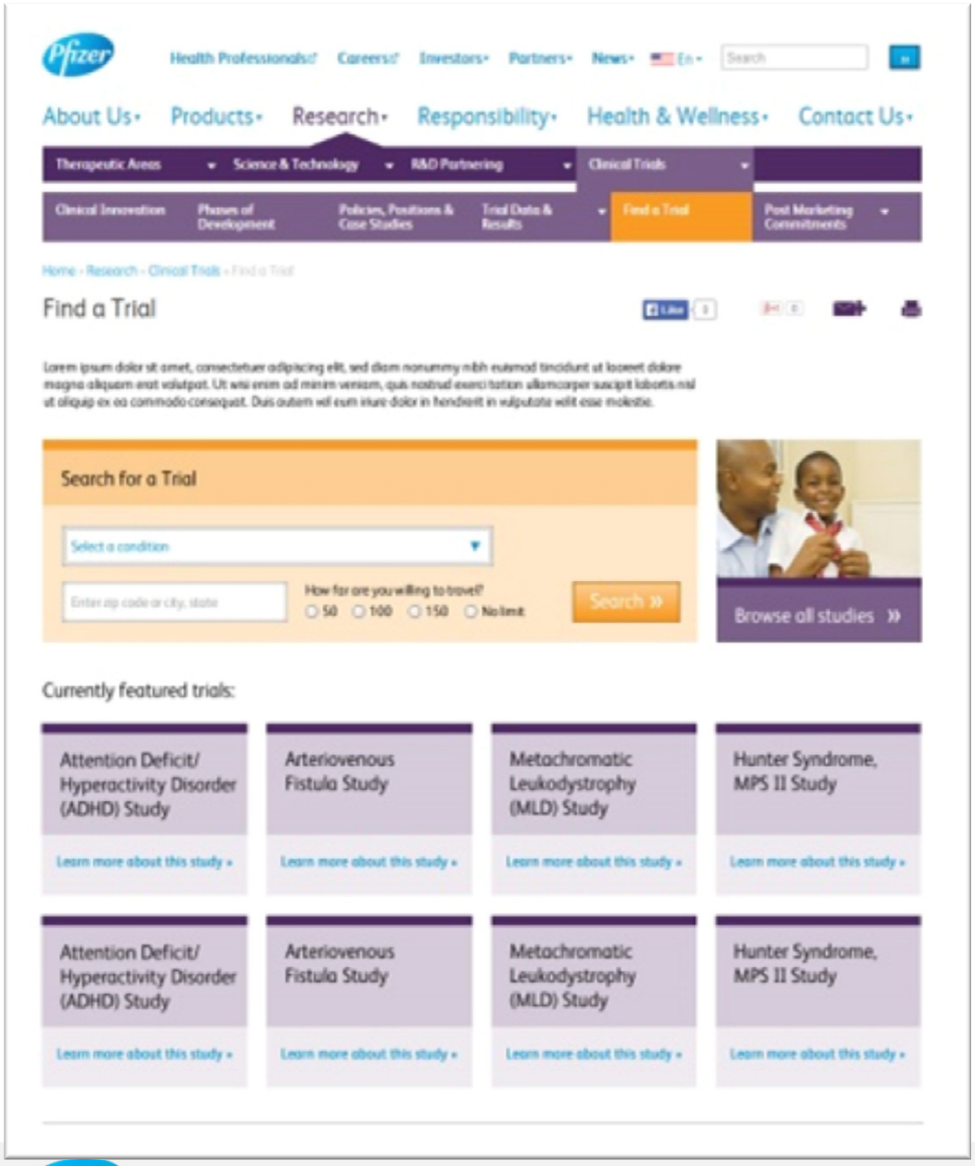
Pfizer is Leading in using Blue Button to Return Clinical data to Study Participants

- Provide patient "deliverables" at study end for increased patient empowerment
- Improve engagement
- Encourage recruitment retention
- Impact care coordination and outcomes

Pfizer.com

Principle #4
Sharing clinical trial information

Pfizer.com / Clinical Trials Redesign: Sharing clinical trial information



Multi-layered, new functionality of Clinical Trials landing site

Robust Pfizer.com / Clinical Trials with links to;

- Trial Searches
- Protocol Pages
- Clinical Team Spaces
- Pfizer Link alumni community, information for potential participants and investigators
- Authoritative sources of study results

Conclusion

- There are 5 commitments in PhRMA / EFPIA Principles for Responsible Clinical Trial Data Sharing.
- Pfizer policy follows the “Principles for Responsible Data Sharing” issued by PhRMA / EFPIA in July 2013.
  - Under our Policy: Pfizer is sending easy-to-understand summaries of clinical trial results to the trial participants.

    <Patient Lay Summary>
- Pfizer is 1st Pharma to Launch Blue Button Pilot Giving Patients in our Studies their Electronic Clinical Data.

Thank you
for your attention

Multi-sponsor request website clinicalstudydatarequest.com

Yoichi Higashibeppu, Eisai

Contents of my part

1. What is CSDR (Clinical Study Data Request.com)?
   What is going on outside Japan?
   - A new way of cooperation between industry and academia -

2. Sponsor Specific Information in CSDR

3. View Available Clinical Studies in CSDR

Examples --- Before Starting what's CSDR:

Websites: Data Sharing Initiatives

http://www.abbvie.com/research-innovation/clinical-trials-data-and-information-sharing/data-and-information-sharing-with-qualified-investigators.html

abbvie

http://bms.com/clinical_trials/pages/disclosure.aspx

Bristol-Myers Squibb

http://www.novonordisk-trials.com/website/content/how-to-access-clinical-trial-datasets.aspx

Novo Nordisk

http://wwwext.amgen.com/about/data_sharing_research_proposal.html

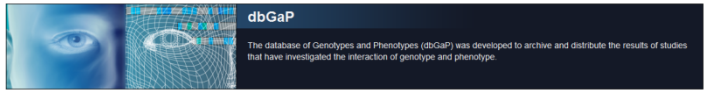
Amgen

http://www.pfizer.com/research/clinical_trials/trial_data_and_results/data_requests

Pfizer

https://www.celgene.com/research-development/clinical-trials/clinical-trials-data-sharing/

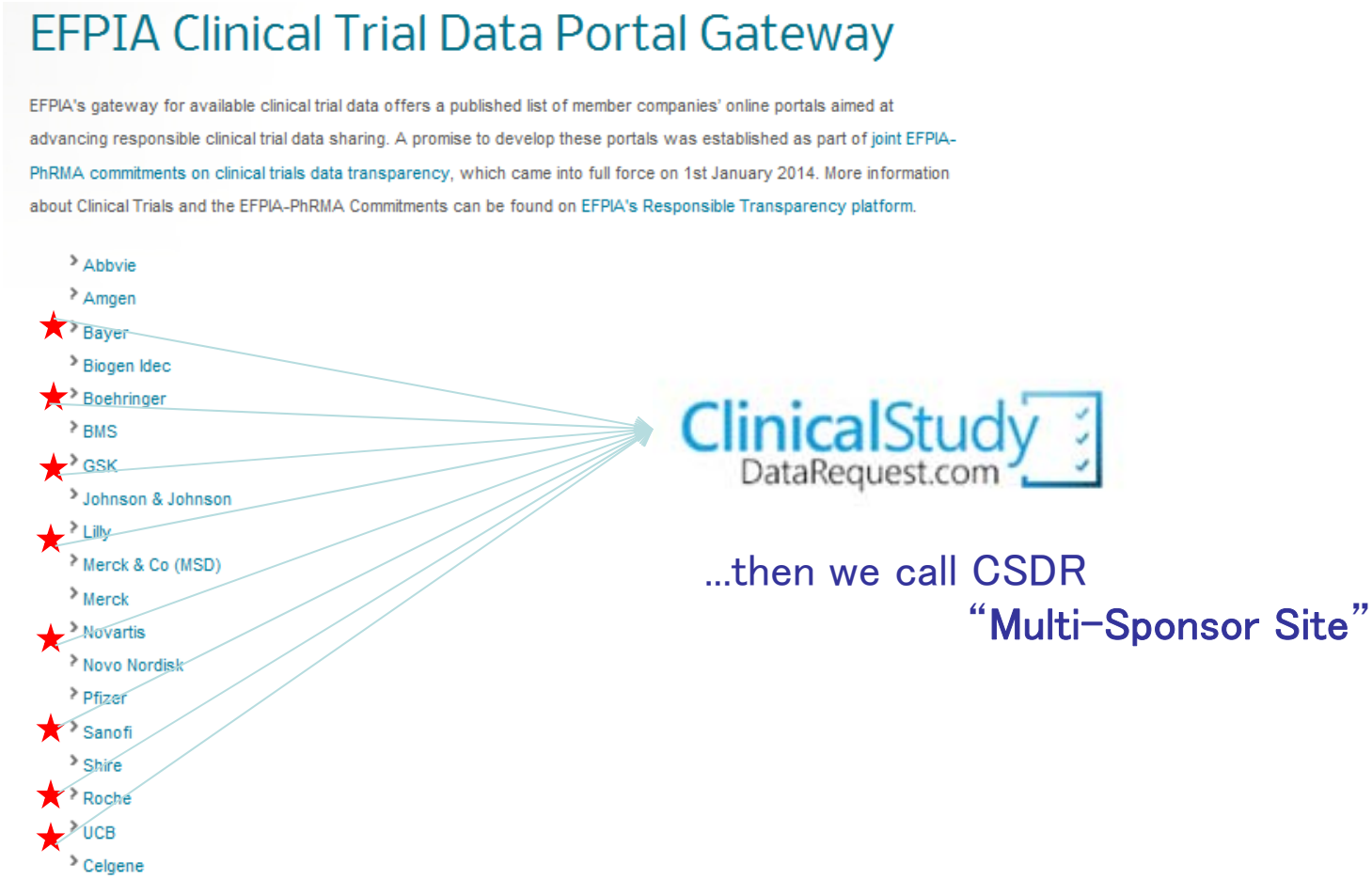
Celgene



Examples --- Before Starting what's CSDR:

EFPIA Clinical Trial Data Portal Gateway

http://transparency.efpia.eu/responsible-data-sharing/efpia-clinical-trial-data-portal-gateway

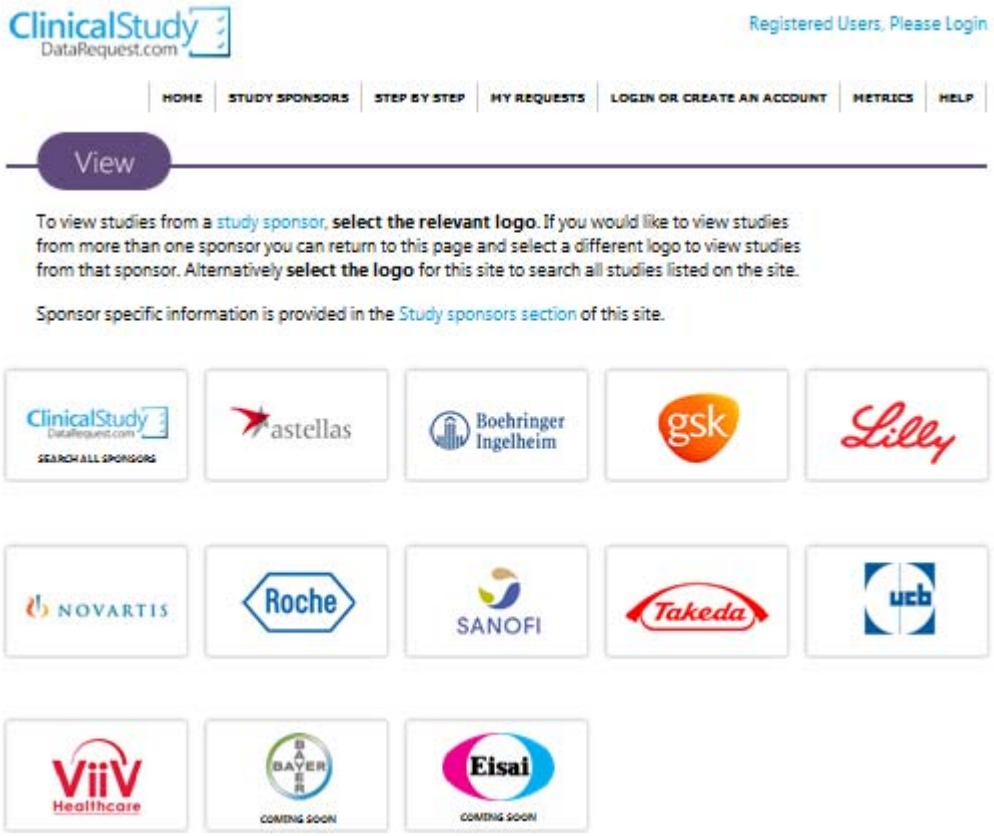


...then we call CSDR

"Multi-Sponsor Site"

What is CSDR?

May 2013, GSK -> Jan 2014 Multi-Sponsor Site



13 companies
(as of June 2015)

N ENGL J MED 371;22 NEJM.ORG NOVEMBER 27, 2014

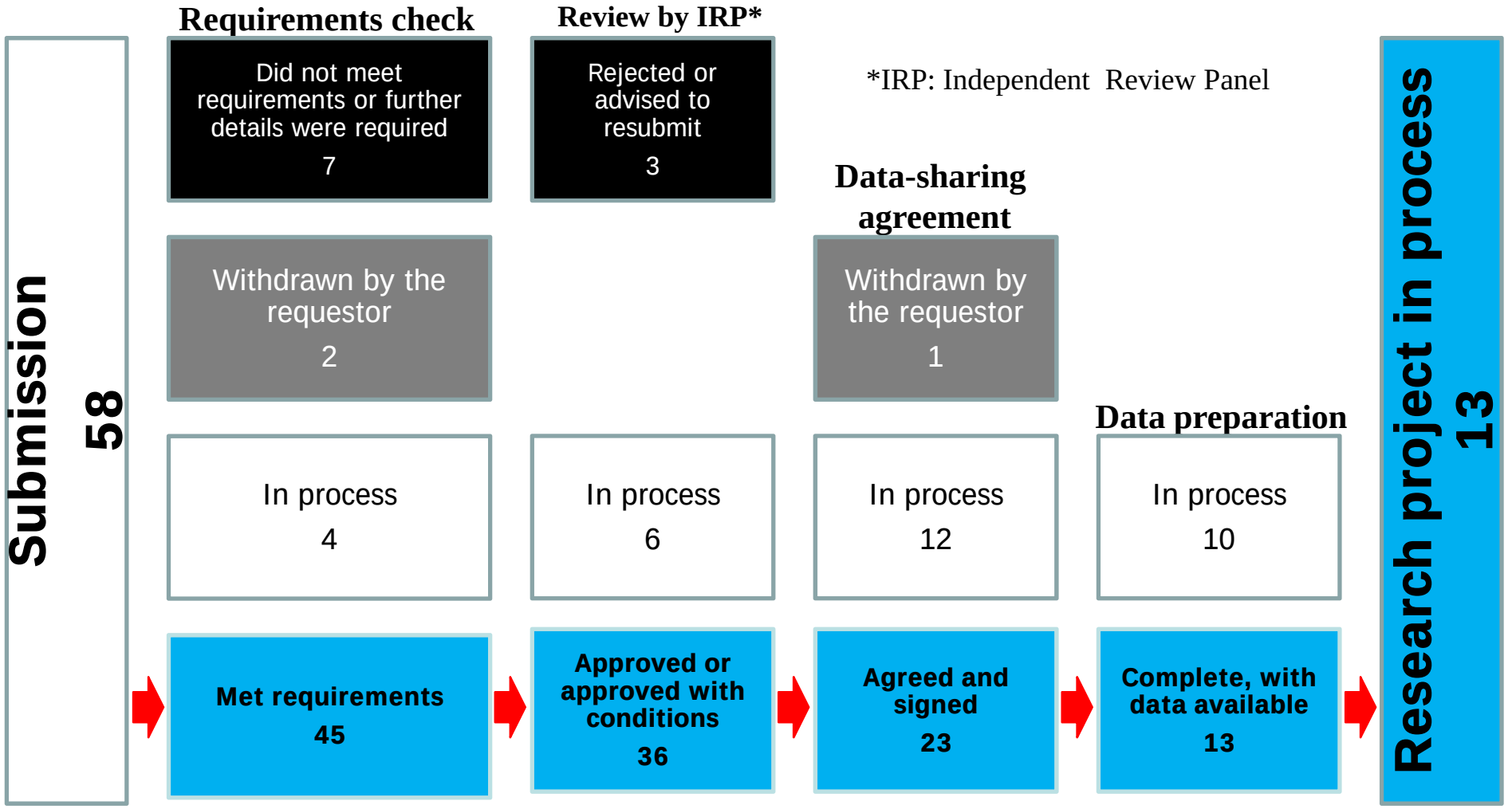
The New England Journal of Medicine

2013/5/7～2014/5/31

Data Sharing, Year 1

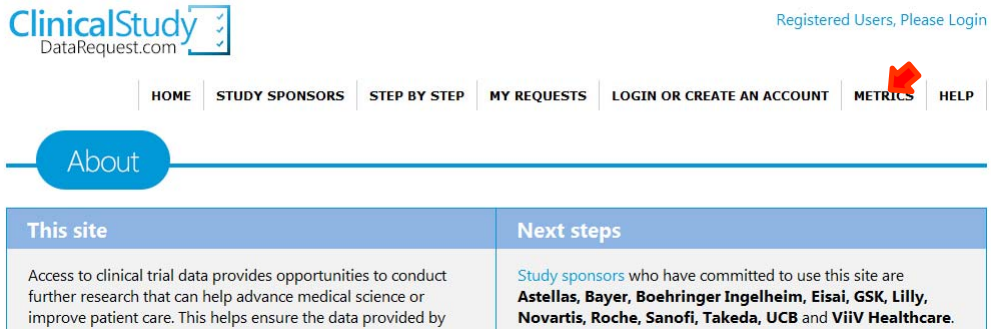
Access to Data from Industry-Sponsored Clinical Trials

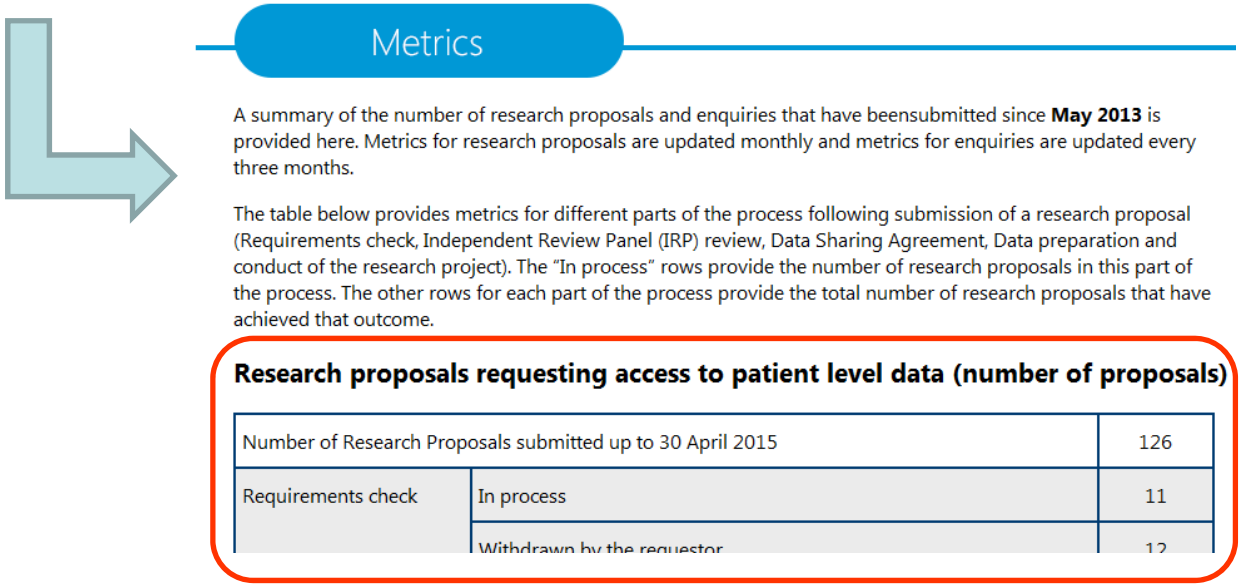
N Engl J Med 2014; 371:2052-2054November 27, 2014



You can follow Updated Metrics of CSDR

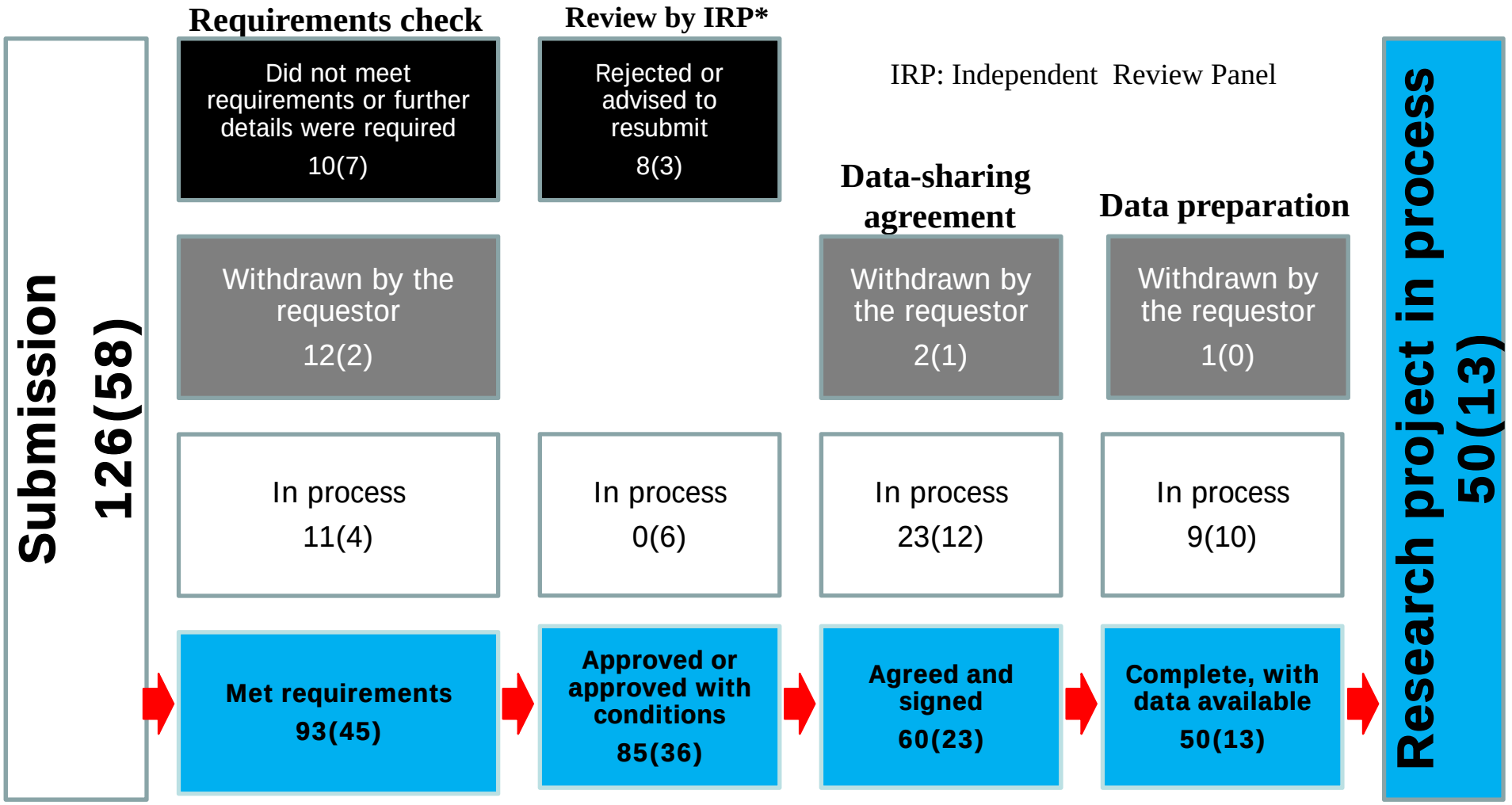
https://www.clinicalstudydatarequest.com/Default.aspx





2013/5/7～2015/4/30
(2013/5/7～2014/5/31)

Update Metrics



You can follow details of Research Proposals

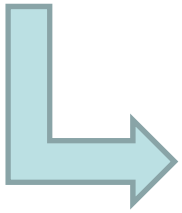
Metrics

A summary of the number of research proposals and enquiries that have beensubmitted since **May 2013** is provided here. Metrics for research proposals are updated monthly and metrics for enquiries are updated every three months.

The table below provides metrics for different parts of the process following submission of a research proposal (Requirements check, Independent Review Panel (IRP) review, Data Sharing Agreement, Data preparation and conduct of the research project). The "In process" rows provide the number of research proposals in this part of the process. The other rows for each part of the process provide the total number of research proposals that have achieved that outcome.

Research proposals requesting access to patient level data (number of proposals)

Number of Research Proposals submitted up to 30 April 2015		126
Requirements check	In process	11
	Withdrawn by the requestor	12
Data Sharing Agreement	In process	23
	Withdrawn by the requestor	2
	Not agreed (not signed)	0
	Agreed (signed) View details of these research proposals	60
Data preparation	In process	9



Metrics

◂ Back

The table below provides details of approved research proposals that have signed Data Sharing Agreements.

Proposal number	Study sponsor(s)	Title	Lead researcher	
611	GSK	Long-acting beta2-agonists for chronic obstructive pulmonary disease	Kayleigh Kew	Further Details
		Predictive and Prognostic Value of		

Examples: Agreed Research Proposals

	Title
Risk factors and Biomarkers	Validation study on magnitude of tumor shrinkage as a prognostic marker
Methodological	The Development of Toxicity Prediction Tools to Assist Oncologists in the Management of Adverse Events in Patients Receiving Treatment with Lapatinib
Comparing treatment regimens	Antiepileptic drug monotherapy for epilepsy: an overview of systematic reviews and network meta-analysis
Optimizing treatments	Relationship of Activated Clotting Time and Bleeding Related Outcomes in the FUTURA OASIS-8 Trial
Co-morbidities/Lifestyle factors	Factors influencing immune response and patient outcomes following influenza vaccination
Re-analysis of GSK study	A multi-center, double-blind, placebo controlled study of paroxetine and imipramine in adolescents with unipolar major depression - efficacy and adverse outcomes

What do you think the figures?

答：Number of …

0 / 59

in Clinical Study Data request.com
as of April 30, 2015

What do you think the figures?

25		25		9	
US	21	UK	7	Australia	5
Canada	4	Spain	4	Jordan	2
		Netherlands	3	India	1
		Germany	2	Taiwan	1
		Italy	2		
		Sweden	2		
		Switzerland	2		
		Belgium	1		
		Denmark	1		
		Germany	1		

答：Number of Agreed (signed) Proposals

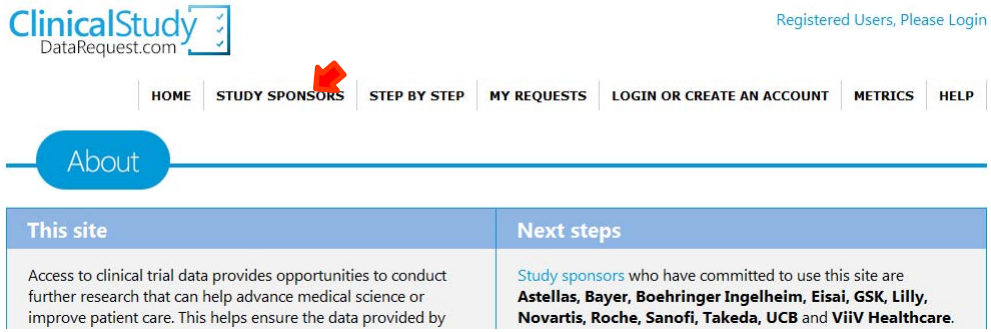
Research proposals requesting access to patient level data

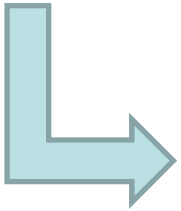
Japan ⇒ 0 / 59

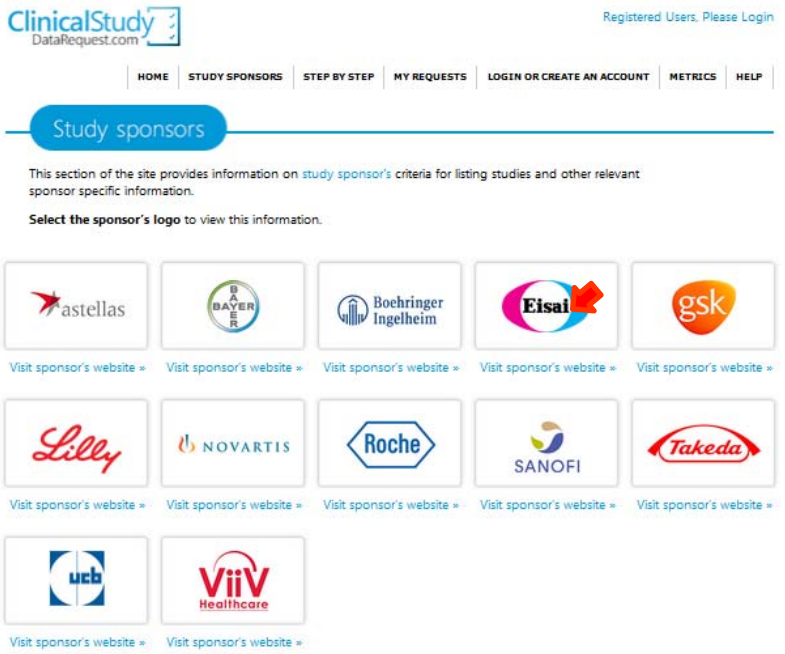
in Clinical Study Data request.com
as of April 30, 2015

Sponsor Specific Information in CSDR 1

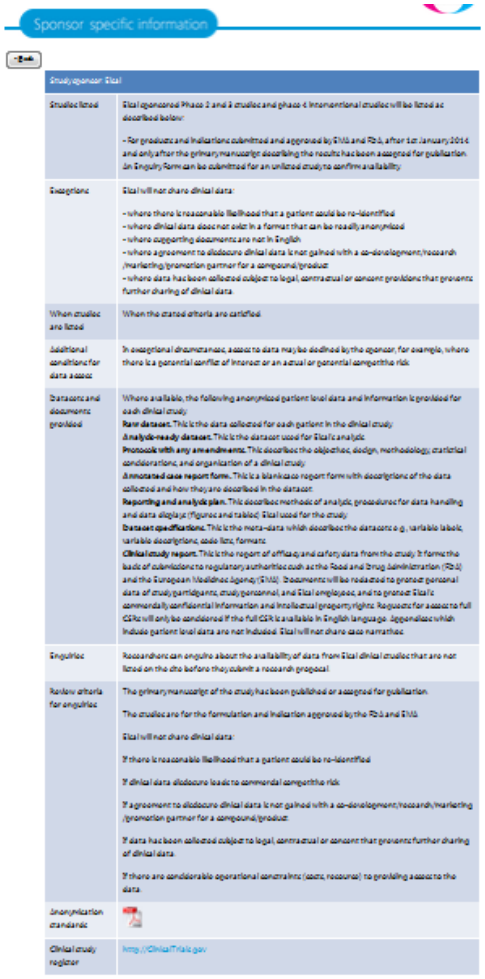
https://www.clinicalstudydatarequest.com/Default.aspx







Sponsor Specific Information in CSDR 2



Sponsor specific information

Study sponsor: Eisai	
Studies listed	Eisai sponsored Phase 2 and 3 studies and phase 4 interventional studies will be listed as described below: - For products and indications submitted and approved by EMA and FDA, after 1st January 2014 and only after the primary manuscript describing the results has been accepted for publication. An Enquiry form can be submitted for an unlisted study to confirm availability.
Exceptions	Eisai will not share clinical data: - where there is reasonable likelihood that a patient could be re-identified - where clinical data does not exist in a format that can be readily anonymized - where supporting documents are not in English - where agreement to disclosure clinical data is not gained with a co-development/research /marketing/promotion partner for a compound/product - where data has been collected subject to legal, contractual or consent provisions that prevents further sharing of clinical data
When studies are listed	When the stated criteria are satisfied
Additional conditions for data access	In exceptional circumstances, access to data may be declined by the sponsor, for example, where there is a potential conflict of interest or an actual or potential competitive risk
Datasets and documents provided	Where available, the following anonymized patient level data and information is provided for each clinical study: **Raw datasets.** This is the data collected for each patient in the clinical study **Analysis-ready datasets.** This is the dataset used for Eisai's analysis **Protocols with any amendments.** This describes the objectives, design, methodology, statistical considerations, and organization of a clinical study **Annotated case report form.** This is a blank case report form with descriptions of the data collected and how they are described in the dataset **Reporting and analysis plan.** This describes methods of analysis, procedures for data handling and data displays (figures and tables) Eisai used for the study **Dataset specifications.** This is the meta-data which describes the datasets e.g., variable labels, variable descriptions, code lists, formats **Clinical study report.** This is the report of efficacy and safety data from the study. It forms the basis of submissions to regulatory authorities such as the Food and Drug Administration (FDA) and the European Medicines Agency (EMA). Documents will be redacted to protect personal data of study participants, study personnel, and Eisai employees, and to protect Eisai's commercially confidential information and intellectual property rights. Requests for access to full CSRs will only be considered if the full CSR is available in English language. Appendices which include patient level data are not included. Eisai will not share case narratives
Enquiries	Researchers can enquire about the availability of data from Eisai clinical studies that are not listed on the site before they submit a research proposal
Review criteria for enquiries	The primary manuscript of the study has been published or accepted for publication. The studies are for the formulation and indication approved by the FDA and EMA. Eisai will not share clinical data: If there is reasonable likelihood that a patient could be re-identified If clinical data disclosure leads to commercial competitive risk If agreement to disclosure clinical data is not gained with a co-development/research/marketing /promotion partner for a compound/product If data has been collected subject to legal, contractual or consent that prevents further sharing of clinical data. If there are considerable operational constraints (costs, resources) to providing access to the data.
Anonymization standards	
Clinical study register	http://ClinicalTrials.gov

- Studies listed
- Exceptions
- When studies are listed
- Additional conditions for data access
- Datasets and documents provided
- Enquiries
- Review criteria for enquiries
- Anonymisation standards
- Clinical study register

Eisai: Sponsor Specific Information in CSDR 1

Studies listed	Eisai sponsored Phase 2 and 3 studies and phase 4 interventional studies will be listed as described below: • For products and indications submitted and approved by EMA and FDA, after 1st January 2014 and only after the primary manuscript describing the results has been accepted for publication. An Enquiry Form can be submitted for an unlisted study to confirm availability.
Exceptions	Eisai will not share clinical data: • where there is reasonable likelihood that a patient could be re-identified • where clinical data does not exist in a format that can be readily anonymised • where supporting documents are not in English • where agreement to disclosure clinical data is not gained with a co-development/research/marketing/promotion partner for a compound/product • where data has been collected subject to legal, contractual or consent provisions that prevents further sharing of clinical data.
When studies are listed	When the stated criteria are satisfied.
Additional conditions for data access	In exceptional circumstances, access to data may be declined by the sponsor, for example, where there is a potential conflict of interest or an actual or potential competitive risk.

Eisai: Sponsor Specific Information in CSDR 2

Datasets and documents provided	Where available, the following anonymised patient level data and information is provided for each clinical study. **Raw dataset.** This is the data collected for each patient in the clinical study. **Analysis-ready dataset.** This is the dataset used for Eisai's analysis. **Protocols with any amendments.** This describes the objectives, design, methodology, statistical considerations, and organisation of a clinical study. **Annotated case report form.** This is a blank case report form with descriptions of the data collected and how they are described in the dataset. **Reporting and analysis plan.** This describes methods of analysis, procedures for data handling and data displays (figures and tables) Eisai used for the study. **Dataset specifications.** This is the meta-data which describes the datasets e.g., variable labels, variable descriptions, code lists, formats. **Clinical study report.** This is the report of efficacy and safety data from the study. It forms the basis of submissions to regulatory authorities such as the Food and Drug Administration (FDA) and the European Medicines Agency (EMA). Documents will be redacted to protect personal data of study participants, study personnel, and Eisai employees, and to protect Eisai's commercially confidential information and intellectual property rights. Requests for access to full CSRs will only be considered if the full CSR is available in English language. Appendices which include patient level data are not included. Eisai will not share case narratives.

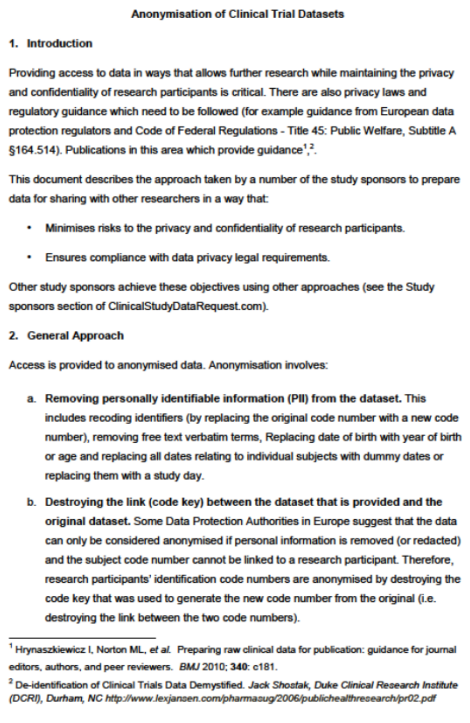
Eisai: Sponsor Specific Information in CSDR 3

Enquiries	Researchers can enquire about the availability of data from Eisai clinical studies that are not listed on the site before they submit a research proposal.
Review criteria for enquiries	The primary manuscript of the study has been published or accepted for publication. The studies are for the formulation and indication approved by the FDA and EMA Eisai will not share clinical data: • If there is reasonable likelihood that a patient could be re-identified • If clinical data disclosure leads to commercial competitive risk. • If agreement to disclosure clinical data is not gained with a co-development/research/marketing/promotion partner for a compound/product. • If data has been collected subject to legal, contractual or consent that prevents further sharing of clinical data. • If there are considerable operational constraints (costs, resource) to providing access to the data.
Anonymisation standards	Next page
Clinical study register	http://ClinicalTrials.gov

Anonymisation
linical trial datas

Eisai: Sponsor Specific Information in CSDR 4

Anonymisation of Clinical Trial Datasets



Anonymisation of Clinical Trial Datasets

1. Introduction

Providing access to data in ways that allows further research while maintaining the privacy and confidentiality of research participants is critical. There are also privacy laws and regulatory guidance which need to be followed (for example guidance from European data protection regulators and Code of Federal Regulations - Title 45: Public Welfare, Subtitle A §164.514). Publications in this area which provide guidance[1,2].

This document describes the approach taken by a number of the study sponsors to prepare data for sharing with other researchers in a way that:

- Minimises risks to the privacy and confidentiality of research participants.
- Ensures compliance with data privacy legal requirements.

Other study sponsors achieve these objectives using other approaches (see the Study sponsors section of ClinicalStudyDataRequest.com).

2. General Approach

Access is provided to anonymised data. Anonymisation involves:

a. **Removing personally identifiable information (PII) from the dataset.** This includes recoding identifiers (by replacing the original code number with a new code number), removing free text verbatim terms, Replacing date of birth with year of birth or age and replacing all dates relating to individual subjects with dummy dates or replacing them with a study day.

b. **Destroying the link (code key) between the dataset that is provided and the original dataset.** Some Data Protection Authorities in Europe suggest that the data can only be considered anonymised if personal information is removed (or redacted) and the subject code number cannot be linked to a research participant. Therefore, research participants' identification code numbers are anonymised by destroying the code key that was used to generate the new code number from the original (i.e. destroying the link between the two code numbers).

[1] Hrynaszkiewicz I, Norton ML, *et al.* Preparing raw clinical data for publication: guidance for journal editors, authors, and peer reviewers. *BMJ* 2010; **340**: c181.

[2] De-identification of Clinical Trials Data Demystified. *Jack Shostak, Duke Clinical Research Institute (DCRI), Durham, NC http://www.lexjansen.com/pharmasug/2006/publichealthresearch/pr02.pdf*

1

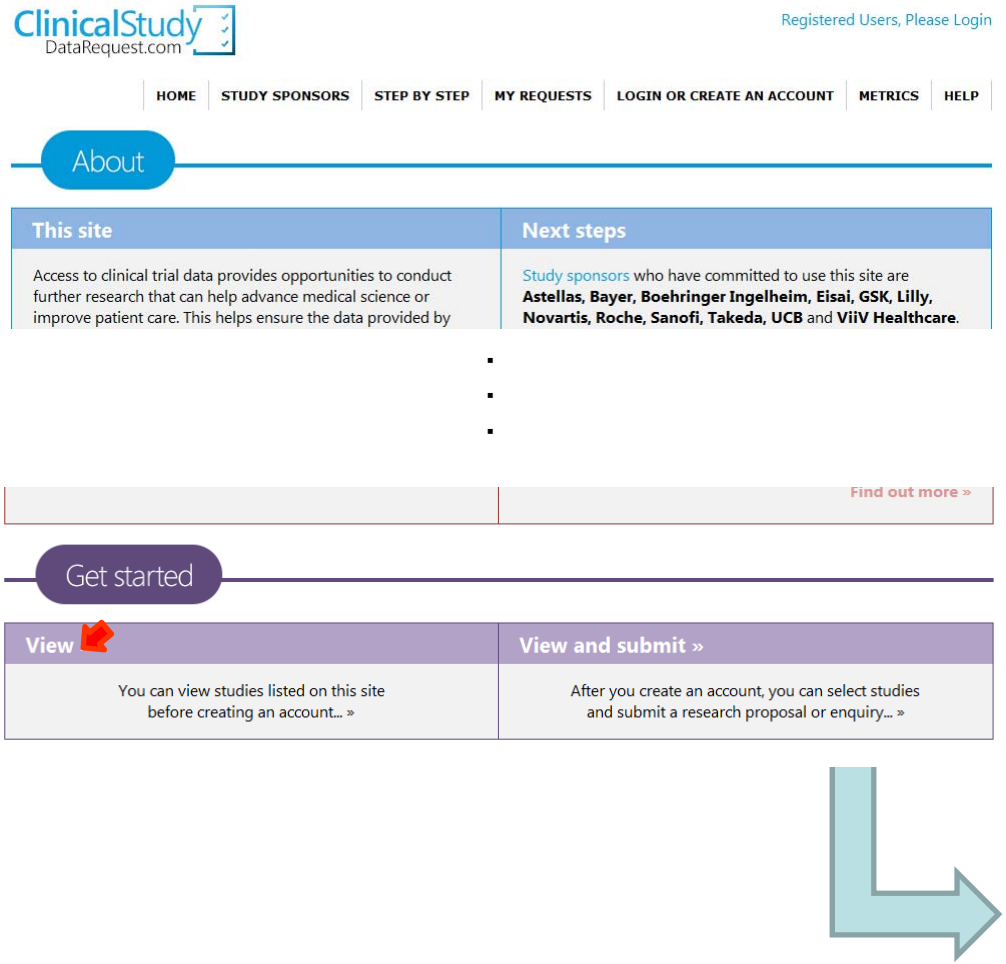
1. Introduction
2. General Approach
3. Removing personally identifiable information (PII) from the dataset
4. Review and Quality Control
5. Destroying the link (key code) between the dataset that is provided and the original dataset

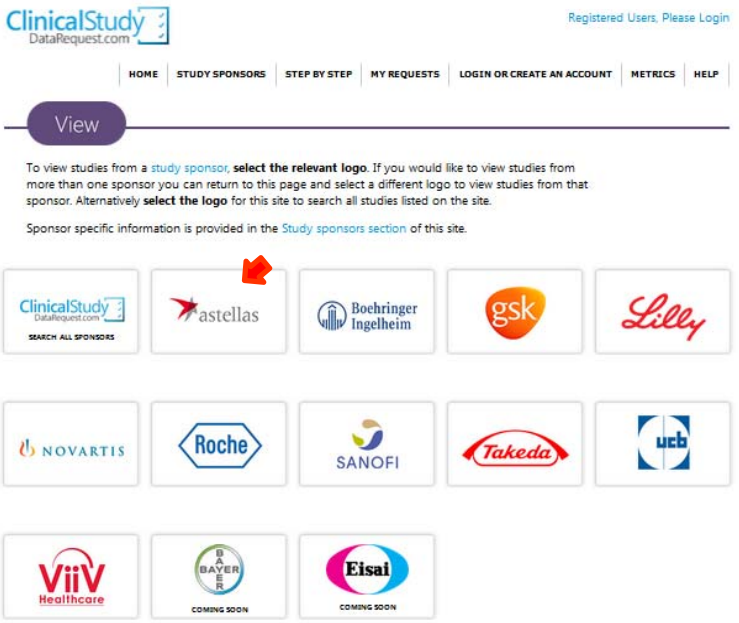
Appendix 1:
A non - real example illustrating removal of personally identifiable information using the dummy date method

Appendix 2:
A non - real example illustrating removal of personally identifiable information using the study day method and aggregation of small centres

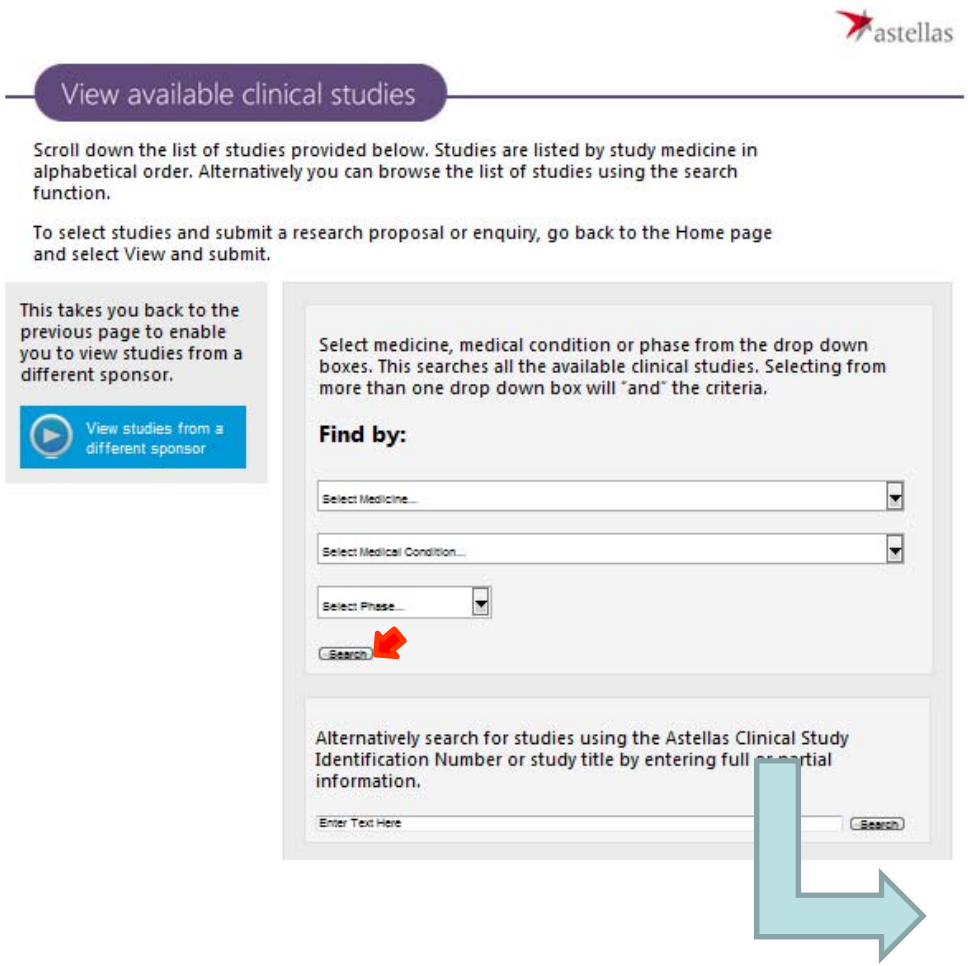
View Available Clinical Studies in CSDR 1

https://www.clinicalstudydatarequest.com/Default.aspx





View Available Clinical Studies in CSDR 2



View Available Clinical Studies in CSDR 3

CT Phase Distribution of DataRequest.com (as of June 5, 2015)

	Ph1	Ph1/2	Ph2	Ph2/3	Ph3	Ph4	sum	(Japan)
Takeda	225	3	39	7	87	6	**367**	14
Roche	0	0	27	0	76	8	**111**	0
BI	17	1	53	0	143	58	**272**	7
GSK	230	0	222	1	572	214	**1239**	18
Lilly	0	0	43	3	97	25	**168**	0
Novartis	0	0	0	0	6	0	**6**	0
UCB	0	0	4	0	17	0	**21**	0
ViiV	0	0	13	3	24	7	**47**	0
Astellas	0	0	2	0	11	0	**13**	0
Sanofi	0	0	0	0	2	0	**2**	0
Bayer **Eisai**	Coming soon							
sum	**472**	**4**	**403**	**14**	**1035**	**318**	**2246**	**39**

Summary

We’ve introduced …

1. Summary of the questionnaire survey

2. Challenge example in ”3. Sharing Results with Patients Who Participate in Clinical Trials”

3. Multi-sponsor request website clinicalstudydatarequest.com

JPMA-DS-TF8 continuously stimulates discussion on “Clinical Trial Data Sharing” in Japan from the standpoint of Data Science.