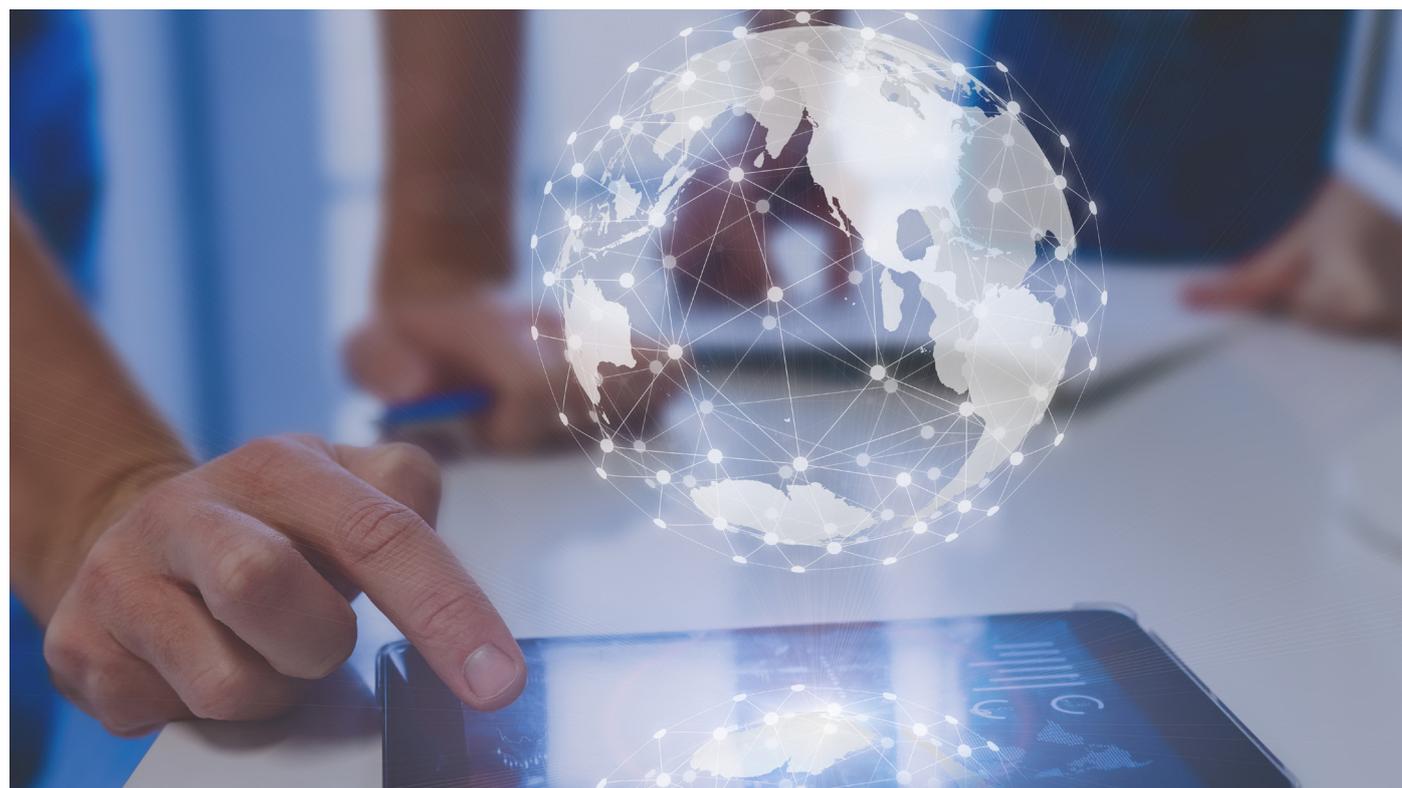
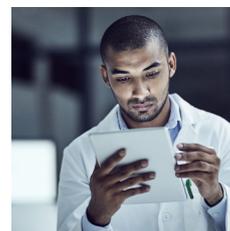
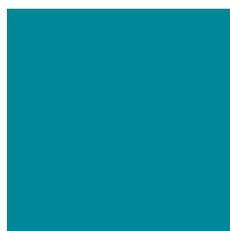
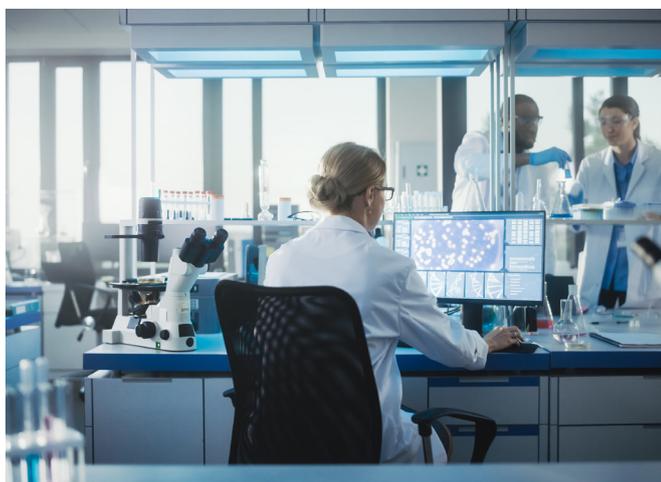




EFPIA SURVEY AMONG MEMBER COMPANIES ON COMPLIANCE WITH THE EFPIA-PHRMA PRINCIPLES FOR RESPONSIBLE CLINICAL TRIAL DATA SHARING

REPORT ON THE 2021 MEMBER COMPANY SURVEY



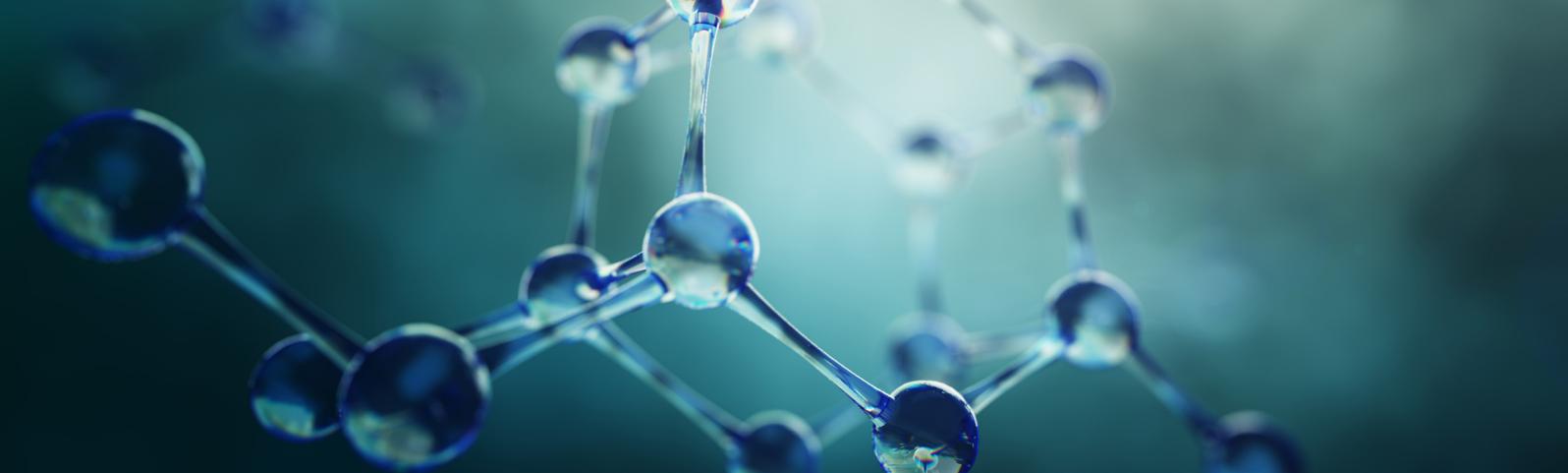
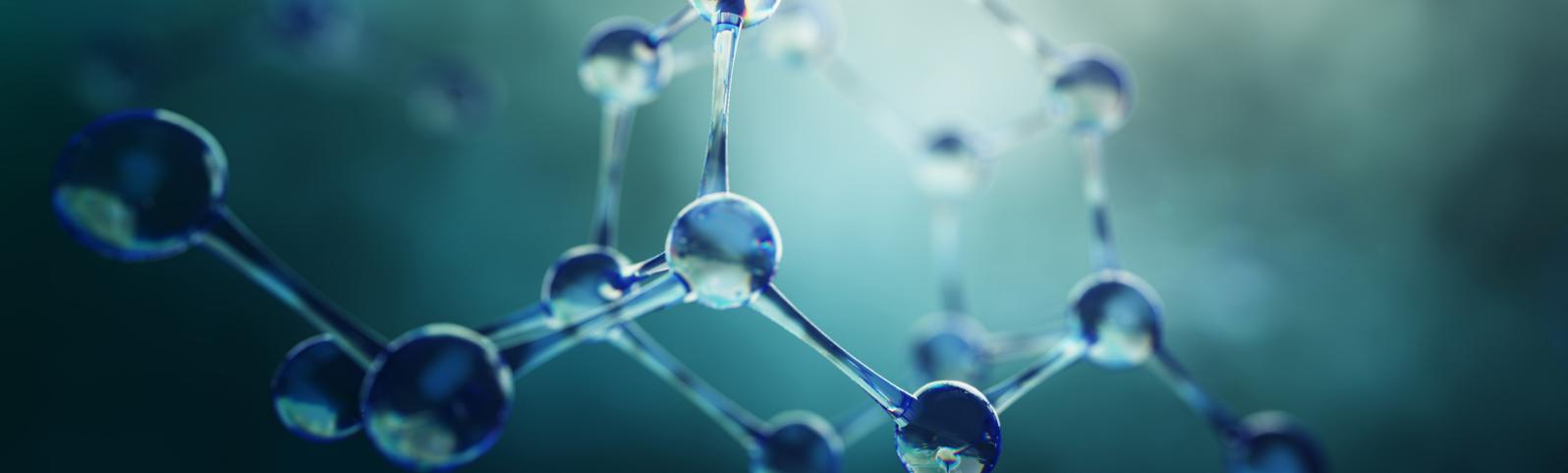


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EXECUTIVE SUMMARY

EFPIA MEMBERS CONTINUE TO BE COMMITTED TO RESPONSIBLE CLINICAL TRIAL DATA SHARING, FOR THE BENEFIT OF PATIENTS AND RESEARCHERS

Transparency, and access to results, of clinical studies are ethical obligations that we as industry take seriously. On 1st January 2014, EFPIA/PhRMA published their [Principles for Responsible Clinical Trial Data Sharing](#) subsequently referred to the “Principles” which demonstrate industry’s commitment to support innovation and to comply with and go beyond the legal requirements of clinical trial data sharing in both the European and US based member companies.

Since then, a lot has happened in the transparency environment for clinical trials. For example, EMA has published in 2016 their [Clinical Data Publication policy \(formerly called Policy 70\)](#) and as of 31st January 2022 the [EU Clinical Trials Regulation 536/2014](#) has come into application. Both significantly increased the transparency requirements for trial sponsors. The COVID-pandemic has also underlined the need for rapid comprehensive publication of clinical trial results to maintain public trust and to enable healthcare professionals to assess the newest scientific evidence in a timely manner. EMA exceptional transparency measures addressed the information needs of the public during a major health crisis. At the same time, the surge of interest has raised ethical questions about the appropriate timing of data sharing, e.g. while studies are still ongoing, as the scientific validity of the final results of the trial might be negatively impacted.

In order to assess the status of the implementation of the Principles among member companies, EFPIA conducted a survey of compliance during July-September 2020. This action followed an earlier survey that was conducted in 2016 and underlines the dedication of the trade association to carefully monitor the progress of industry-led commitments. Adherence to the jointly agreed policies such as the Principles is required for each company to become, and stay, a member of EFPIA. All companies with at least one-year of EFPIA membership and one product marketed both in EU and US were asked to complete the survey to monitor the current status of compliance to the principles. Through this survey the members were also requested to provide information on additional transparency measures they are taking that go beyond the Principles. The Principles focus on sharing of results once products have obtained regulatory approval in EU and US. The scope of the survey therefore related to 34 EFPIA member companies (with at least one year of membership), out of which 100% eventually responded to the survey. The questionnaire was also sent to 17 Small and Medium Sized companies (SMEs) affiliated to EFPIA (14) and Vaccines Europe (3). Only 1 SME (affiliated to Vaccines Europe – specialized group within EFPIA) was within the scope (products marketed



in US and EU) and their response has been taken in consideration in the totality of the results. In total, 35 responses were received (34 EFPIA companies and 1 SME affiliated to Vaccines Europe).

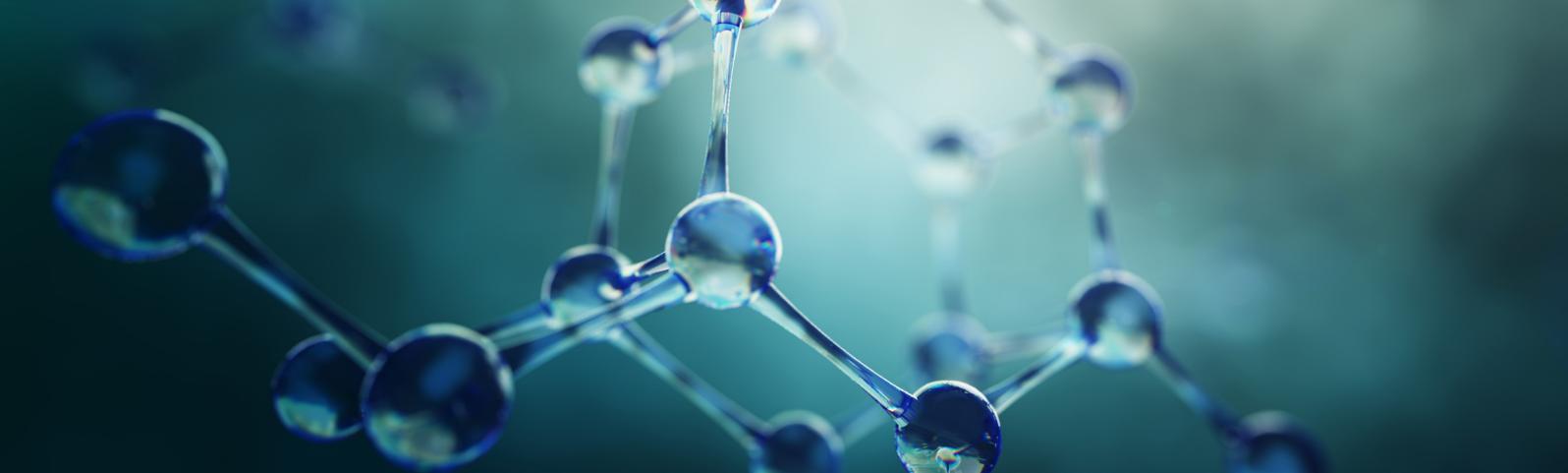
The following 5 aspects were investigated:

1. Enhancing data sharing with researchers
2. Enhancing public access to clinical study information - CSR synopsis availability
3. Sharing results with patients who participate in clinical trials – lay summaries
4. Certifying procedures for sharing clinical trial information
5. Reaffirming commitments to publish clinical trial results.

CONCLUSIONS

- The compliance rate to the 5 EFPIA-PhRMA Principles was generally very high, however, some aspects did not reach 100%.
- Challenges with the implementation of the Principles were seen in specific process demands in regard to data sharing. Overall, companies commit to the data sharing but new technologies and platforms for different ways of sharing data have evolved since the origin of the Principles.
- A large proportion of companies report disclosure and data sharing activities that go beyond the commitments, such as providing Lay Language Summaries (also referred to by some sponsors as Trial Result Summaries or Plain Language Summaries) to trial participants and/or the general public.
- 100% compliance with the legal requirements of ClinicalTrials.gov, EudraCT and EU Clinical Trials registries was reported by members.

EFPIA and its member companies are committed to responsible clinical data sharing and are looking forward to continued engagement with the stakeholders to ensure transparency of clinical trial data while safeguarding patient privacy, respecting the integrity of national regulatory systems, and maintaining incentives for investment in biomedical research. We keep evaluating our members' commitment to the Principles and are working with our members to revise some content of the Principles to align with the ever-changing legislative and policy environment of clinical trials transparency and data sharing.



CONTENT

INTRODUCTION AND BACKGROUND

EFPIA conducted an electronic survey of the compliance on EFPIA-PhRMA Principles for Responsible Clinical Data Sharing among member companies during July to September 2020. This was subsequent to a survey that was conducted in 2016 and underlines the dedication of EFPIA trade association to carefully monitor the progress on industry-led initiatives.

METHOD

Survey was distributed as a Survey Monkey questionnaire to EFPIA members who had been members of EFPIA for more than a year (members are allowed one year to implement the EFPIA/PhRMA Principles of Responsible Data Sharing).

Furthermore, the Principles outline transparency measures for products that are on the market in either EU or US, thus companies which do not have products marketed both in EU and US were out of scope.

Among the 34 EFPIA member companies with more than one year of membership and which are in scope as described above, the initial response rate was 94%, after 2 reminders and follow-up the response rate reached 100%. The questionnaire was also sent to 17 SMEs affiliated to EFPIA (14) and Vaccines Europe (3). Only one SME response was within the scope (with products marketed in US and EU). This response is part of the survey results, and it is affiliated to Vaccines Europe. Vaccines Europe is a specialized vaccines group within EFPIA. 35 responses were received in total (34 EFPIA companies and 1 SME affiliated to Vaccines Europe).

After receiving the initial response, members whose answers revealed a level of non-compliance in one or several Principles were contacted individually to clarify the requirements and clarify potential misunderstandings. The data shown in this report include results including agreed policy amendments.

The set of questions asked are divided in this report into each of the individual commitments in the Principles for responsible data sharing. In addition, some questions were asked to further compile information on additional transparency measures that member companies might have implemented beyond the five Principles. All survey questions can be seen in full in the Appendix.

RESULTS

PRINCIPLE 1. ENHANCING DATA SHARING WITH RESEARCHERS

Principle 1 is covered by 14 different Questions and all questions allowed free text for further specifications and details.

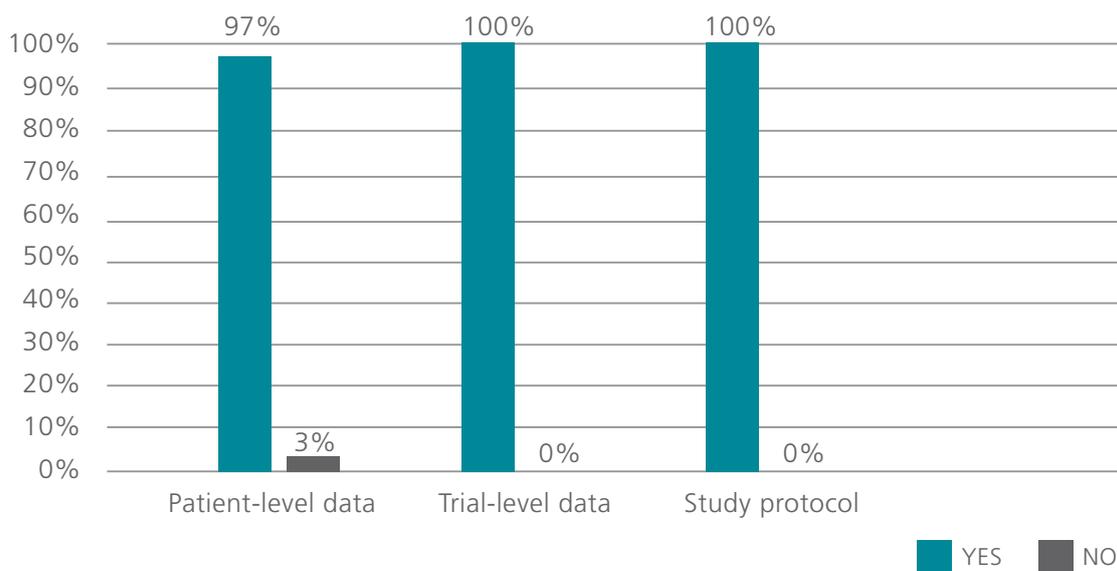
Questions Q6 to Q8, are for assessing compliance with Principle 1, part 1. And Q9 for assessing data sharing beyond the Principle 1, part 1 requirements.

Q6: Is your company sharing (anonymised) patient-level data from clinical trials in patients for medicines and indications with market authorisation in EU and US?

Q7: Is your company sharing (anonymised) trial-level data from clinical trials in patients for medicines and indications with market authorisation in EU and US?

Q8: Is your company sharing (anonymised) study protocols from clinical trials for medicines and indications with marketing authorisation in EU and US?

Only one company reported not sharing data 97% (Q6). For the other two elements of the Principles, compliance was 100% (Q7 and Q8)



Q9: Is your company sharing data beyond the previous items? E.g., for substances in development, closed developments, trials in healthy volunteers.

A total of 27 (77%) companies replied that in some specific circumstances they were sharing data beyond the Principles.

The categories specified were:

- discontinued projects
- phase I/healthy volunteers
- clinical documents
- trials from before 2014
- non-interventional studies

The Questions 10-13 assessed compliance with Principle 1, part 2. And Question 14 on additional information, not part of the compliance with Principle 1, part 2.

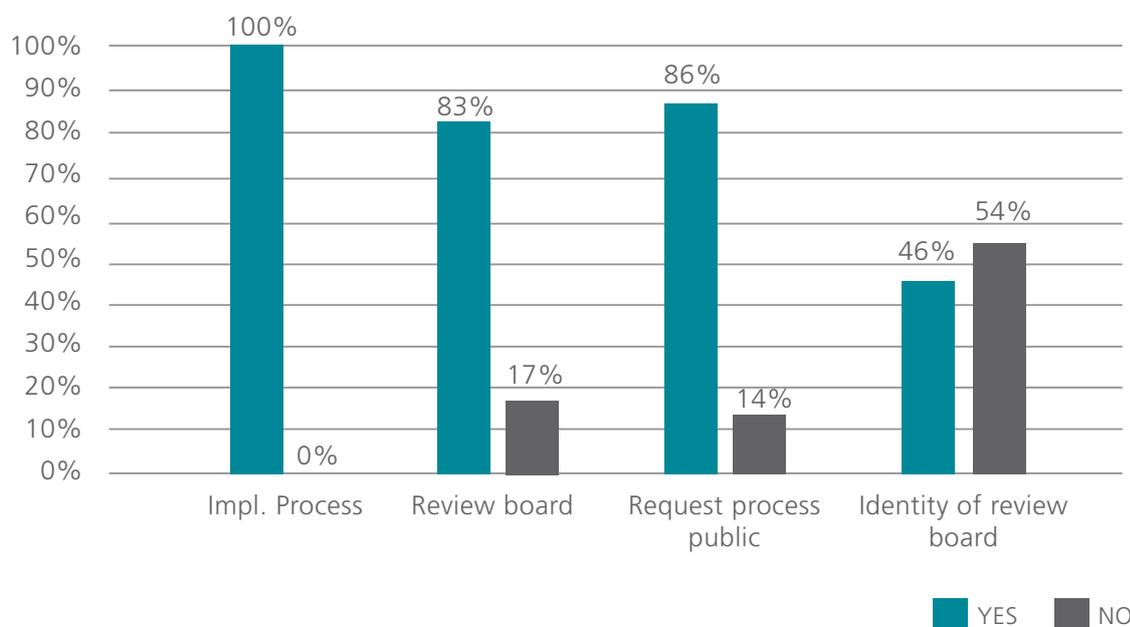
Q10: Has your company implemented a system to receive and review research proposals and provide applicable data and protocols to help facilitate scientific and medical research?

Q11: Has your company established a scientific review board to assess the validity of research proposals?

Q12: Has your company publicly posted your data sharing request review process?

Q13: Has your company made the identity of the members of your scientific review board publicly available, including any existing relationships between your company and the board members?

All respondents have implemented a process (100%) (Q10). However, the question related to the individual process elements (Q11, Q12 and Q13) were in several cases answered with a “No” because sponsors have implemented a multi-sponsor platform solution or other ways for sharing data. This result demonstrates that the Principles need updating to include alternative ways for sharing data.



This result demonstrates that the Principles need updating to include alternative ways for sharing data.

Q14: Additional information requested, these are not part of the 5 EFPIA/PhRMA Principles for EFPIA companies to be compliant with. See answers below:

	Is making data requestors aware of the applicable limitations, e.g. that data may not be made available because of privacy issues in the informed consent or danger of patient re-identification and other legal constraints.	Requests researchers who generate results from shared data to make them publicly available, e.g. as a scientific publication	Is making researchers aware that the data must not be shared with third parties and that all efforts must be taken to prevent potential re-identification of patients.
Yes	32	33	34
No	3	2	1
Yes %	91%	94%	97%

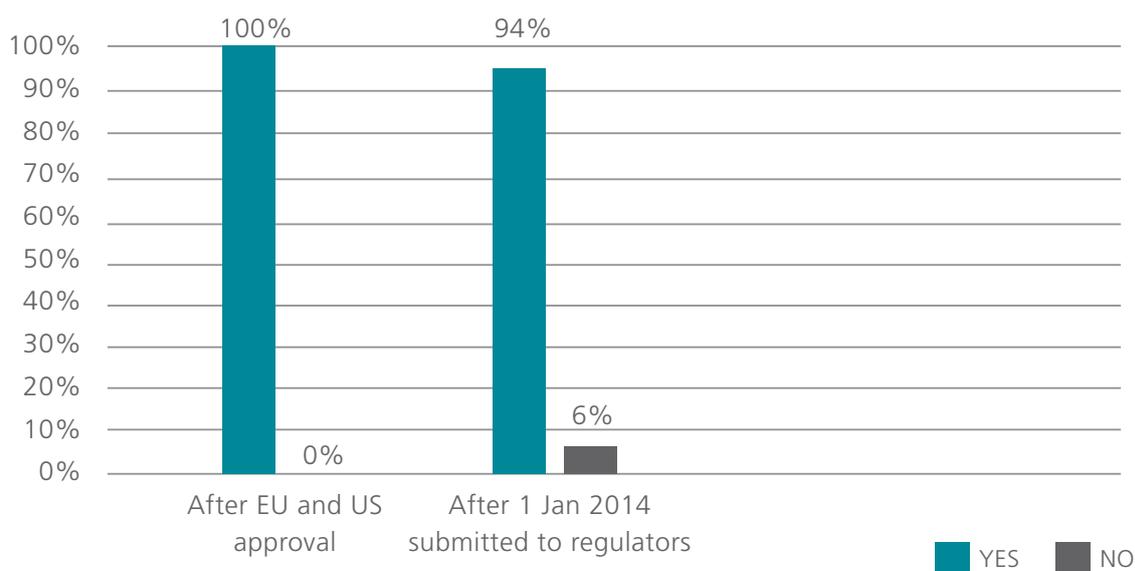
PRINCIPLE 2. ENHANCING PUBLIC ACCESS TO CLINICAL STUDY INFORMATION

Principle 2 is covered by two compliance related questions and two questions requesting additional information.

Q15: Is your company making Clinical Study Report (CSR) synopses available for clinical trials in patients following marketing authorization in US and EU?

Q16: Is your company making available CSR synopses for studies completed after 1 January 2014 and that have been submitted to regulators?

All 35 companies (100%) are reporting that they share the synopses after EU and US approval and 29 (94%) are committed to publish CSR synopsis since Jan 2014. During a follow-up exercise after the initial survey response, the remaining EFPIA companies have clarified that they are setting up policies to comply with publication of CSR synopsis for completed studies by end of 2021.



Further information was requested by two additional questions which were beyond compliance with the Principles.

Q17: Is your company additionally making CSR synopses available of studies with investigational products that have not yet been approved in any country?

Q18: Is your company applying redactions to the CSR synopses that you make available?

	Making Synopses available for products that have not been approved in any country?	Apply redaction to Synopses?
Yes	18 (51%)	28 (80%)
No	17 (49%)	7 (20%)

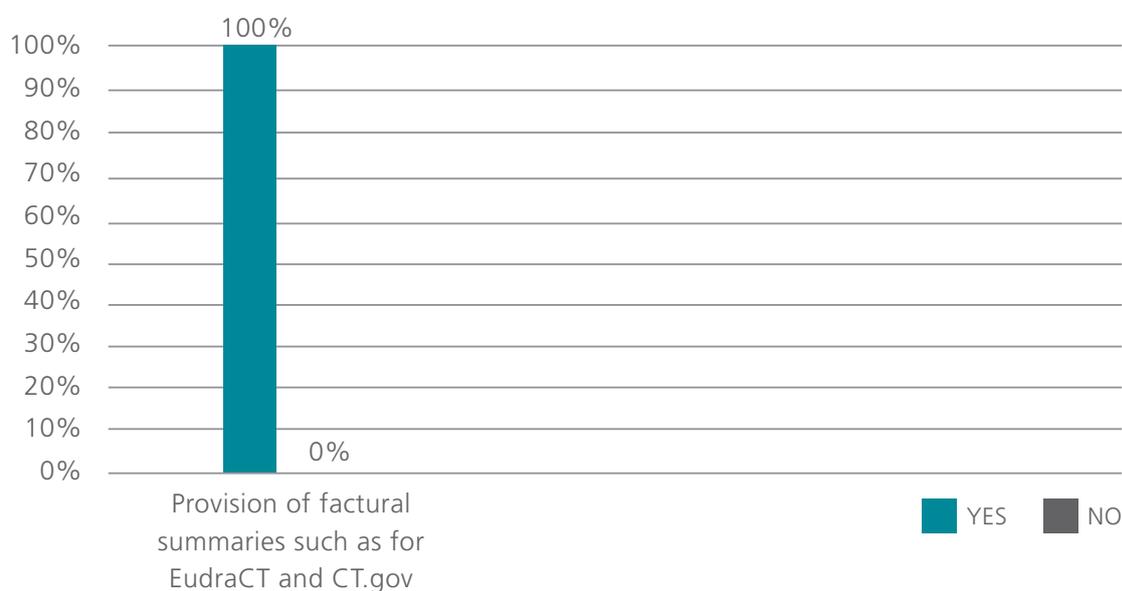
Companies that report they are sharing CSR synopses beyond what is required by the Principles state that they make data available for discontinued projects, and that they provide results tables as required by international trial registries, such as Clinicaltrials.gov and for the EU Clinical Trials Register.

PRINCIPLE 3. SHARING RESULTS WITH PATIENTS WHO PARTICIPATE IN CLINICAL TRIALS

Compliance of principle 3 was assessed by 1 single question:

Q19: Is your company sharing factual summaries of clinical trial results (such as the data posted on EudraCT/ EU CT Register or clinicaltrials.gov)?

All companies responded yes, i.e., 35, 100% compliance.



Two additional questions were asked to gather information on how companies prepare for the upcoming implementation of the EU CT Regulation which will make it mandatory to provide [Lay Summaries](#) of the results of clinical trials.

As the provision of Lay Summaries will be an obligation once the EU Clinical Trials Regulation is implemented, we would like to understand how far company members have come in the process of providing lay summaries?

Q20: Is your company routinely producing lay (language) summaries?

Q21: Does your company have a process in place for producing lay (language) summaries?

	Routinely Provide Lay Language Summaries	Have a process in place
Yes	22 (63%)	25 (71%)
No	13 (37%)	10 (29%)

Companies without a process have provided the following reasons:

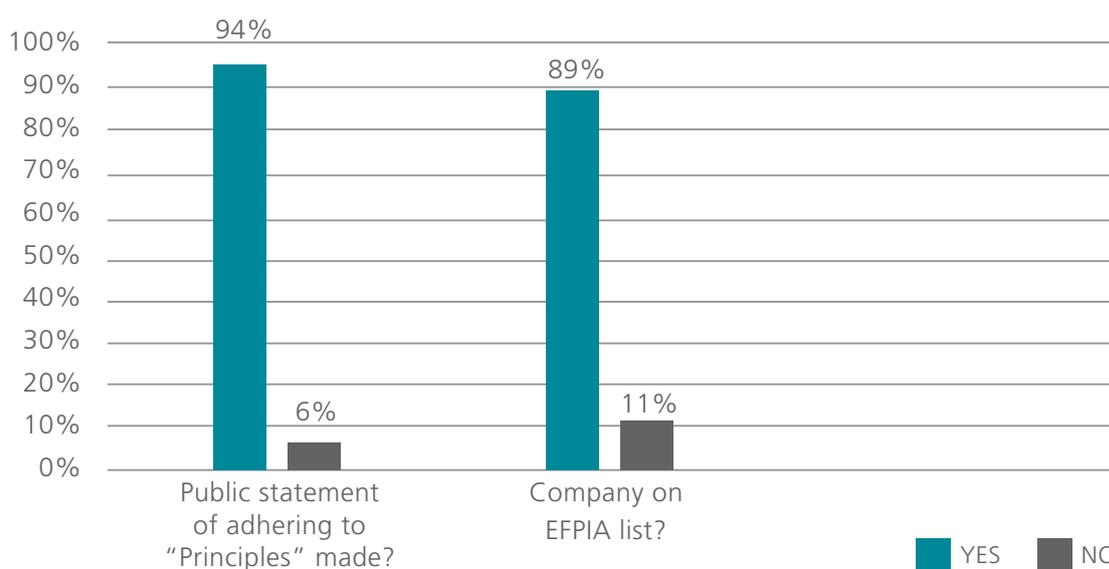
- process is being piloted
- not producing them routinely
- lack of resources
- process is in development
- no policy yet.

PRINCIPLE 4. CERTIFYING RESULTS WITH PATIENTS WHO PARTICIPATE IN CLINICAL TRIALS

Two questions are included to assess compliance with principle 4.

Q22: Has your company made public statements of adhering to the ‘Principles of responsible Data Sharing’?

Q23: If so, is your company’s name on the EFPIA list of such companies?



A total of 33 (94%) companies answered they had made a public statement and 31 (89%) that they were listed on the EFPIA website.

EFPIA has reached out to member companies to ensure inclusion in the list on [EFPIAs website](#).

PRINCIPLE 5. REAFFIRMING COMMITMENTS TO PUBLISH CLINICAL TRIAL RESULTS

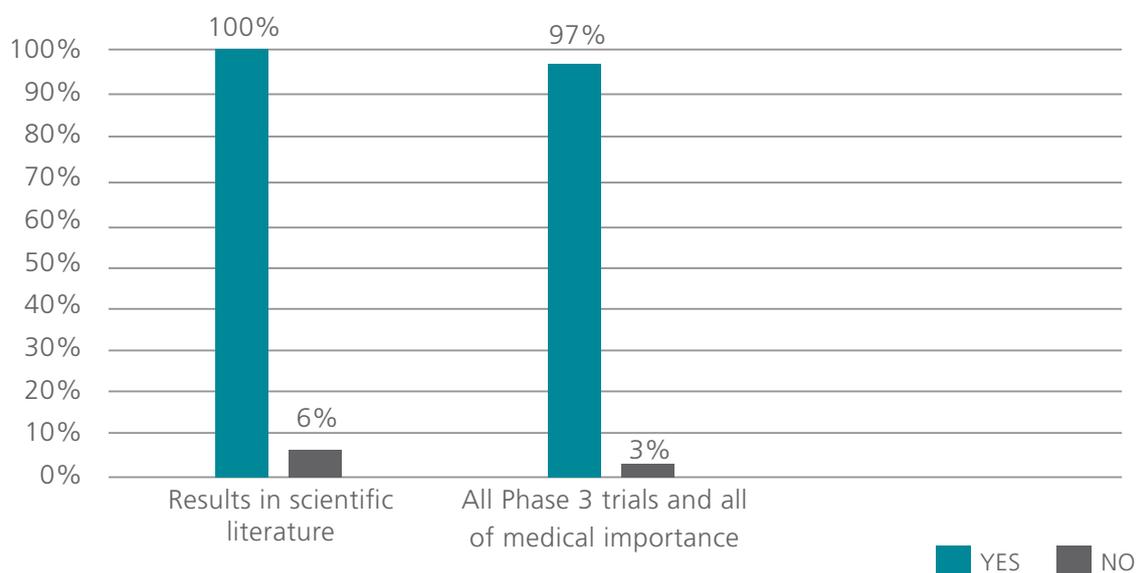
The last of the five Principles deals with the central commitment to publish results from clinical trials.

Two additional questions were used to assess compliance and a further two questions asked for more detailed information about the commitments made by member companies that go beyond the Principles.

Q24: Is your company committed to publication of clinical trial results in the scientific literature irrespective of whether the results of the clinical trials are positive or negative?

Q25: Has your company made a commitment to publish all phase III trial results and all trial data of significant medical importance?

All companies 35 (100%) answered yes to question 24 that they were committed to publication of clinical trial results in the scientific literature irrespective of whether the results of the clinical trials are positive or negative. And all but one 34 (97%) companies replied that they had made a commitment to publish all phase III trial results and all trial data of significant medical importance.



The two additional questions for sharing practices beyond the Principles were:

Q26: Does your company encourage publication of clinical trial data and results regardless of clinical phase and marketing authorization status?

Q27: Does your company have a position with regards to the voluntary sharing of results from non-interventional/observational studies?

	Encourage publication of results regardless of clinical phase	Position on voluntary sharing of results for non-interventional/observational studies
Yes	28 (80%)	30 (86%)
No	7 (20%)	5 (14%)

Comments in relation to publishing results state:

- only safety studies [are published]
- put on ClinicalTrials.gov
- only interventional [are published]
- individual decision
- put on EU PAS

OVERALL COMPLIANCE RESULTS AND INITIATIVES AFTER THE SURVEY

The overall compliance was high and has been further improved by this survey. After the survey, clarifications have led individual EFPIA member companies to put policies and corrective measures in place to further improve their compliance with the Principles.

HIGH LEVEL OF TRANSPARENCY COMMITMENTS BEYOND CURRENT PRINCIPLES

	Yes	No	Comment
Data sharing - beyond Principle 1	77%	23%	Yes for: <ul style="list-style-type: none"> discontinued projects phase I/healthy volunteers clinical documents trials from before 2014 non-interventional studies
Sharing synopses of results - beyond Principle 2	51%	49%	Yes for: <ul style="list-style-type: none"> for discontinued projects results tables as required in registries
Lay person summaries – beyond Principle 3 <ul style="list-style-type: none"> Already preparing Lay Language Summaries Process in place for preparing 	63% 71%	37% 29%	No, why: <ul style="list-style-type: none"> piloting not routinely lack of resources process in development no policy yet
Publications of results – beyond principle 5 <ul style="list-style-type: none"> Publication of results regardless of clinical phase and MA status Sharing of results from non-interventional studies 	80% 86%	20% 14%	No, why: <ul style="list-style-type: none"> only safety studies put on ClinicalTrials.gov only interventional individual decision put on EU PAS

ACKNOWLEDGMENTS

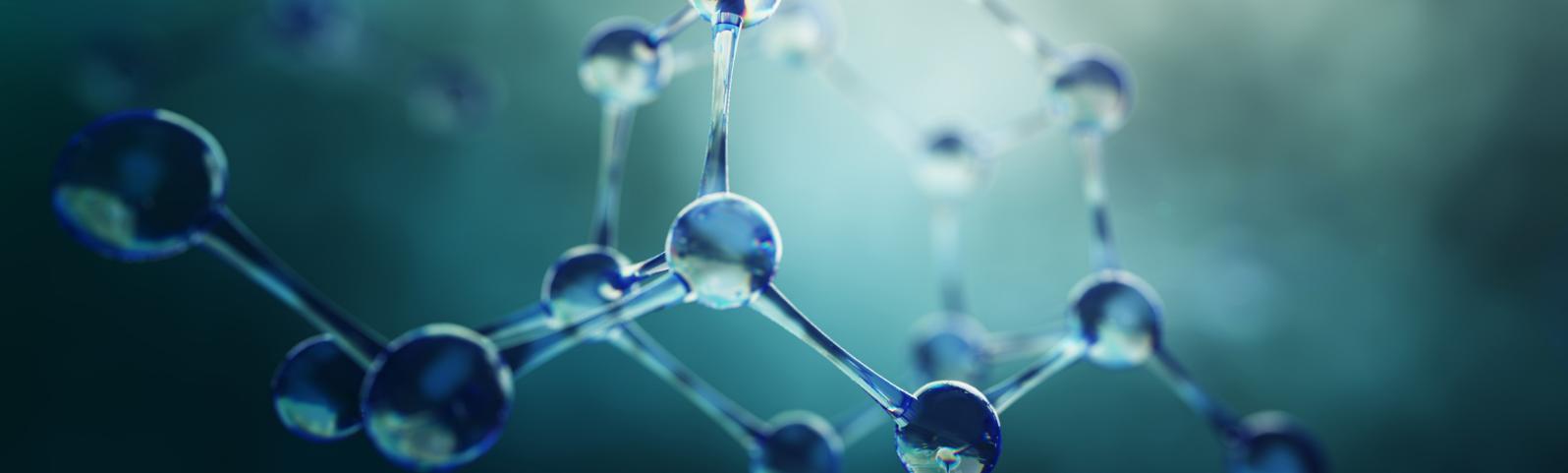
EFPIA wants to thank the following collaborators who have contributed in authoring this report: Merete Jørgensen (formerly Novo Nordisk), Thomas Schindler (formerly Boehringer-Ingelheim Pharma, now BioNTech SE), Nick Sykes (Pfizer), Wendy Wimmer (MSD), Julie Holtzople (AstraZeneca) and Silvia García (EFPIA Secretariat).

REFERENCES

[Principles for Responsible Clinical Trial Data Sharing](#)

[Sharing clinical trial information](#)

[Guest blog: Enhancing public health through responsible Clinical Trials Data Sharing](#)



GLOSSARY

EFPIA	The European Federation of Pharmaceutical Industries and Associations (EFPIA) represents the biopharmaceutical industry operating in Europe. Through its direct membership of 37 national associations, 38 leading pharmaceutical companies and a growing number of small and medium-sized enterprises (SMEs), EFPIA's mission is to create a collaborative environment that enables our members to innovate, discover, develop and deliver new therapies and vaccines for people across Europe, as well as contribute to the European economy.
CLINICAL STUDY REPORT	A clinical study report (CSR) on a clinical trial is a long document giving details about the methods and results of a trial. It is a comprehensive scientific document addressing efficacy and safety data according to an international standard (ICH E3). The content is more detailed than in a peer-reviewed academic paper.
LAY SUMMARIES	Lay summaries are short documents that explain the results of a clinical trial in a language that is understandable for non-experts that is the patients and general public. The requirement for lay summaries for clinical trials was instigated by the EU Clinical Trials Regulation 536/2014.
PATIENT-LEVEL DATA	Information on individual patients collected during a clinical study, including: demographic data, lab results, baseline characteristics, drug concentration, biomarker and pharmacogenetic data, and adverse events experienced.
PROTOCOL	Clinical trial protocols inform investigators on how to run a particular trial, for example, what drug to give and when, what trial measurements to take and when and how to record them, and how to treat and record adverse events. Clinical Trial protocols are written according to ICH E6 (R2).
SPONSOR	A sponsor can be defined as "a person or organization who oversees the clinical study and is responsible for analyzing the study data". The sponsor may be an individual or a pharmaceutical company. The sponsors need to fulfill a great number of regulatory requirements including all pharmacovigilance aspects and ultimately legally responsible for the preparation, conduct and reporting of the clinical trial.
STUDY-LEVEL DATA	Study-level data consist of patient-level data that have been collected, compiled and tabulated, or otherwise organized into study-level data sets, to be used in interpreting the outcome of a clinical study. Study-level data present clinical trial data in an objective manner, without subjective analysis or interpretation, usually in tabular, graphic, or statistical form showing, for example, averaged, stratified, or patterned presentations of study data gathered.
SYNOPSES	Synopses are summaries of more extensive clinical study reports (CSRs) according to ICH E3.

APPENDIX SURVEY QUESTIONNAIRE - VERSION 1- JUNE 11, 2020

Implementation Status of the EFPIA-PhRMA Principles for Responsible Clinical Trial Data Sharing

Introduction

Transparency is one of the key principles pursued by EFPIA and by regulators. To gain insight into the current practices, we initiate this survey as a follow-up to the [survey performed in 2016](#) of the [Joint EFPIA-PhRMA Principles for Responsible Data Sharing](#) which were published 1 Jan 2014.

The purpose of this follow-up survey is to assess the implementation status of the joint principles across EFPIA member companies, including SMEs and Vaccines Europe (VE) members.

EFPIA has a goal that all member companies be 100% compliant with these principles. The aim of collecting this data is to allow the EFPIA to ascertain progress to compliance across the membership and introduce any steps needed to ensure all members can fully implement these Principles. In a similar survey conducted in 2016, the majority of EFPIA member companies were shown to have put processes in place for the implementation of these principles.

The aggregated results are to be presented at the next EFPIA Innovation Board Sponsored Committee meeting in Q4 2020 and EFPIA Secretariat reserves the right to initiate individual discussions with the member company who may, for one reason or another, not have been able to implement the principles according to the commitment. The intention is to make the aggregated results publicly available thereafter to affirm EFPIA member companies' commitment to responsible clinical data sharing.

* 1. Name:

* 2. Company:

* 3. Email

* 4. Affiliation

EFPIA

Vaccines Europe

5. If you are an [SME EFPIA member](#), do you have at least one product on the EU or US market? (If "No", this survey does not apply to you and you do not need to complete it.)

Yes

No



Implementation Status of the EFPIA-PhRMA Principles for Responsible Clinical Trial Data Sharing

Principle 1: Enhancing Data Sharing with Researchers

* 6. Is your company sharing **(anonymised) patient-level data** from clinical trials in patients for medicines and indications with market authorisation in EU and US?

Yes

No

If 'No', please explain why not

* 7. Is your company sharing **(anonymised) trial-level data** from clinical trials in patients for medicines and indications with market authorisation in EU and US?

Yes

No

If 'No', please explain why not

* 8. Is your company sharing **(anonymised) study protocols** from clinical trials in patients for medicines and indications with market authorisation in EU and US?

Yes

No

If 'No', please explain why not

* 9. Is your company sharing **data beyond the previous items**? E.g. for substances in development, closed developments, trials in healthy volunteers.

Yes

No

If 'Yes', please specify:



* 10. Has your company implemented a system to receive and review research proposals and provide applicable data and protocols to help facilitate scientific and medical research?

Yes

No

If 'No', what is hindering your company?

* 11. Has your company established a scientific review board to assess the validity of research proposals?

Yes

No

If 'No', what is hindering your company?

* 12. Has your company publicly posted your data sharing request review process?

Yes

No

If 'No', what is hindering your company?

* 13. Has your company made the identity of the members of your scientific review board publicly available, including any existing relationships between your company and the board members?

Yes

No

If 'No', what is hindering your company?

* 14. Additional information requested, these are not part of the 5 EFPIA-PhRMA principles for EFPIA companies to be compliant with. **Check the boxes next to the statements that apply to your company:**

Your company is making data requesters aware of the applicable limitations, e.g. that data may not be made available because of privacy issues in the informed consent or danger of patient re-identification and other legal constraints.

Your company requests researchers who generate results from shared data to make them publicly available, e.g. as a scientific publication.

Your company is making researchers aware that the data must not be shared with third parties and that all efforts must be taken to prevent potential re-identification of patients.

None of the above.

Implementation Status of the EFPIA-PhRMA Principles for Responsible Clinical Trial Data Sharing

Principle 2: Enhancing Public Access to Clinical Study Information

* 15. Is your company making Clinical Study Report (CSR) synopses available for clinical trials in patients following marketing authorisation in US and EU?

Yes

No

If 'No', what is hindering your company?

* 16. Is your company making available CSR synopses for studies completed after 1 January 2014 and that have been submitted to regulators?

Yes

No

If 'No', what is hindering your company?

* 17. Additional information requested, these are not part of the 5 EFPIA-PhRMA principles for EFPIA companies to be compliant with.

Is your company additionally making CSR synopses available of studies with investigational products that have not yet been approved in any country?

Yes

No

If 'Yes', what are the limitations?

If 'No', what is hindering your company?

* 18. Additional information requested, these are not part of the 5 EFPIA-PhRMA principles for EFPIA companies to be compliant with.

Is your company applying redactions to the CSR synopses that you make available?

Yes

No

If 'Yes', what type of information do you redact?



Implementation Status of the EFPIA-PhRMA Principles for Responsible Clinical Trial Data Sharing

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

* 19. Is your company sharing factual summaries of clinical trials results (such as the data posted on EudraCT or ClinicalTrials.gov) and make these available to research participants?

Yes

No

If 'No', what is hindering your company?

* 20. As the provision of Lay Summaries (summaries of clinical study results in lay language) will be an obligation once the EU Clinical Trials Regulation is implemented, we would like to understand how far company members have come in the process of providing lay summaries.

Is your company routinely producing lay summaries?

Yes

No

If 'No', what is hindering your company?

* 21. Does your company have a process in place for producing lay summaries?

Yes

No

If 'No', does your company have a process defined but not implemented (please answer with **Yes** or **No**)?



Implementation Status of the EFPIA-PhRMA Principles for Responsible Clinical Trial Data Sharing

Principle 4: Certifying Procedures for Sharing Clinical Trial Information

* 22. Has your company made public statements of adhering to the “Principles of responsible data sharing”?

Yes

No

If ‘Yes’, please state where:

* 23. If so, is your company’s name on the [EFPIA list](#) of such companies?

Yes

No

If ‘No’, what is hindering your company?



Implementation Status of the EFPIA-PhRMA Principles for Responsible Clinical Trial Data Sharing

Principle 5: Reaffirming Commitments to Publish Clinical Trial Results

* 24. Is your company committed to publication of clinical trial results in the scientific literature irrespective of whether the results of the clinical trials are positive or negative?

Yes

No

If 'No', what is hindering your company?

* 25. Has your company made a commitment to publish all phase III trial results and all trial data of significant medical importance?

Yes

No

If 'No', which limitations does your company apply?

* 26. Additional information requested, these are not part of the 5 EFPIA-PhRMA principles for EFPIA companies to be compliant with.

Does your company encourage publication of clinical trial data and results regardless of clinical phase and marketing authorisation status?

Yes

No

If 'No', which limitations does your company apply?

* 27. Additional information requested, these are not part of the 5 EFPIA-PhRMA principles for EFPIA companies to be compliant with.

Does your company have a position with regards to the voluntary sharing of results from non- interventional/ observational studies?

Yes

No

Please provide any additional information (**applicable for both Yes and No answers**):



Implementation Status of the EFPIA-PhRMA Principles for Responsible Clinical Trial Data Sharing

Final Comments

28. If you have any comments or suggestions for improvement of clarity on the EFPIA-PhRMA principles on responsible clinical trial data sharing, please provide them here:

