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Before the Committee on Strategies for Responsible Sharing of Clinical Trial Data  

Institute of Medicine  
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The Pharmaceutical Research and Manufacturers of America (PhRMA) and its members are committed to enhancing responsible sharing of clinical trial data produced by biopharmaceutical companies and other research sponsors, and we appreciate the opportunity to provide testimony to the Committee on Strategies for Responsible Sharing of Clinical Trial Data (the Committee).

PhRMA is a voluntary, nonprofit association that represents the country’s leading pharmaceutical research and biotechnology companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives. In 2012, PhRMA members alone invested approximately $50 billion toward discovering and developing new medicines. Accordingly, our companies have a strong interest in advancing innovation through responsible clinical trial data sharing that protects the interests of patients, the integrity of regulatory systems, and the ability to invest in biomedical research.

Executive Summary

PhRMA supports responsible data sharing arrangements that will benefit the public health and long-term ecosystem for medical research. Responsible data sharing can enhance the public health and accelerate development of new medicines by
allowing for independent reanalysis of the rich data sets that sponsors compile in their clinical trials.

PhRMA believes that data sharing arrangements are most appropriately managed by data generators themselves rather than through systems where regulators assume additional responsibilities for administering the disclosure of sponsors’ regulatory submissions. Sponsors can provide clinical trial data and information in a manner that serves the public interest by facilitating independent research, while at the same time protecting both patient privacy as well as incentives for investment in biomedical research. In addition, biopharmaceutical companies encourage both government and academic researchers to engage in responsible data sharing.

To this end, PhRMA and the European Federation of Pharmaceutical Industries and Associations (EFPIA) recently adopted an industry-wide set of commitments set forth in the PhRMA-EFPIA Principles for Responsible Clinical Trial Data Sharing (the Principles) attached in Appendix A.¹ In these Principles, PhRMA and EFPIA members have committed to share patient- and study-level clinical data, protocols, and clinical study reports with qualified researchers pursuing legitimate research projects. Companies also have committed to public disclosure of synopses of their clinical study reports after approval of a new medicine or indication in the U.S. or European Union (EU).

The Principles build upon biopharmaceutical companies’ continuing efforts to enhance the public health through routine publication of clinical research, collaboration with academics, voluntary sharing of clinical trial information and results on public

¹ PhRMA & EFPIA, Principles for Responsible Clinical Trial Data Sharing (2013), available at http://phrma.org/sites/default/files/pdf/PhRMAPrinicplesForResponsibleClinicalTrialDataSharing.pdf
websites, and voluntary sharing of data through data pooling arrangements and consortia. PhRMA also supported Congress’s efforts to increase transparency of clinical trial information in the Food and Drug Administration Amendments Act of 2007 (FDAAA), in which Congress expanded ClinicalTrials.gov and required FDA to release action packages describing the basis for approval of new medicines. We believe that completion of the required Department of Health and Human Services (HHS) rulemaking to expand further ClinicalTrials.gov will also enhance transparency.

PhRMA believes that companies’ commitments to responsible data sharing, adoption of similar standards throughout the research ecosystem, and full implementation of ClinicalTrials.gov are the best means to advance innovation for patients.

I. **Guiding Principles that Underpin the Responsible Sharing of Clinical Trial Data**

Responsible data sharing arrangements should adhere to the following principles:

1. Protect patient privacy
2. Do no harm to the integrity of regulatory systems worldwide; and
3. Maintain incentives to invest in biomedical research and the development of innovative medicines for patients.

**Patient privacy.** Processes for data sharing or disclosure must take account of patients’ informed consent and the reality that patient re-identification may be possible. Respecting patient privacy and informed consent is especially important given the
demonstrated ability to re-identify patients based on anonymized information\(^2\) and the fact that the secondary use of patients’ clinical trial data is not likely within the scope of historical informed consent. As the Committee knows, the terms of individuals’ participation in a clinical trial is established by the informed consent document. If that document sets forth terms that are not consistent with third-party sharing of data gathered during the trial, it would be unethical and disrespectful of patient autonomy to disregard the terms of the informed consent by disclosing such health information more expansively. Moreover, threats to patient privacy protection will jeopardize patient willingness to participate in clinical trials, a clear public health harm.

**Regulatory system integrity.** Random, non-contextualized data re-analysis will result in regulatory second-guessing and decrease confidence in the safety and efficacy of medicines. Dumping millions of pages of clinical trial information into the public domain without providing appropriate scientific and clinical context or guidelines for meta-analysis will ensure that expert regulatory decisions are second-guessed, thereby undermining patient trust and confidence in the safety and effectiveness of approved medicines.

As noted in the summary from the recent IOM workshop on sharing research data, a “risk of data sharing is that reanalysis of data may produce phantom risk and health scares.”\(^3\) As Robert Califf of Duke University Medical Center stated during the previous IOM workshop: “There will be consequences of people being killed by poor use of data because, if it hits the news, a lot of people will stop taking their medications.”\(^4\)

\(^3\) Institute of Medicine, Sharing Clinical Research Data: Workshop Summary 59 (2013).
\(^4\) Id. at 24.
PhRMA shares these concerns, and the PhRMA-EFPIA Principles accordingly limit certain data access to qualified researchers after submission of a legitimate research proposal.

**Incentives for investment in biomedical research.** Indiscriminate release of companies’ clinical and pre-clinical data and information will harm incentives to invest in biomedical research, while providing little or no incremental value to patients and healthcare professionals. Rather, the appropriate sharing of data within the research community must contain protections against public disclosure through a data sharing agreement. Beneficiaries of public disclosure of clinical and pre-clinical information and complete clinical study reports include competitors—including those in countries that do not respect international data exclusivity agreements—who may free-ride off of the investments of innovators. Accordingly, the Federal Courts have recognized that manufacturers have a competitive interest in ensuring that clinical trial data in an NDA are not prematurely released, because requiring disclosure could make it possible for competitors to use the data to seek approval of competing products “without incurring the time, labor, risk, and expense involved in developing them independently.”

Competitors also benefit from learning about other companies’ scientific or commercial strategies, gleaning information to shape their own decisions about developing products for the same condition or with similar mechanisms of action. Accordingly, failing to protect clinical trial data and information from premature disclosure and use by competitors will harm private investment in medical research.

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As a recent IOM report recognized, “disclosure does not equal transparency.”\textsuperscript{6}

The biopharmaceutical industry believes that it is the responsibility of all research sponsors, including academia and the government, to share clinical trial data in a responsible and tailored way that will be meaningful to different audiences, including the research community, members of the public, and patients who participate in biomedical research. Conversely, it is the responsibility of medical product regulators to explain how they assess the benefits and risks of approved treatments.

The PhRMA-EFPIA Principles contain tailored commitments to share clinical trial data prospectively through a set of processes whose implementation will begin on January 1, 2014. We urge all research sponsors to adopt consistent commitments.

II. **Responsible Data Sharing for Distinct Audiences**

Over the past decade, PhRMA and its member companies have taken many steps to promote clinical trial transparency. Most recently, PhRMA and EFPIA member companies jointly adopted the Principles for Responsible Clinical Trial Data Sharing with implementation to begin on January 1, 2014. These Principles include five commitments for sharing information that is tailored to researchers, the public, and research participants.

Biopharmaceutical companies will implement these commitments as a common industry baseline, and we encourage all medical researchers, including those in academia and in the government, to promote medical and scientific advancement by adopting and implementing the following standards:

\textsuperscript{6} Institute of Medicine, Sharing Clinical Research Data: Workshop Summary 6 (2013).
1. **Enhancing Data Sharing with Researchers.** Companies pledge to share, upon request, the following information with scientific and medical researchers conducting legitimate research: patient-level clinical trial data, study-level clinical trial data, and protocols from clinical trials in patients for medicines and indications approved in the U.S. and EU. This commitment to share patient-level and study-level data is tailored to provide relevant information to researchers while also aiming to safeguard patient privacy, regulatory system integrity, and incentives to invest in medical research.

Companies commit to create systems for receipt and review of data sharing requests and to publicly post information about their request review processes. Each company will establish a scientific review board that will include scientists and/or healthcare professionals who are not employees of the company. Members of the scientific review boards will participate in the review of data requests to determine whether they meet criteria designed to ensure appropriate qualifications of the requestor and legitimacy of the research purpose, unless a company makes an initial determination on its own to share applicable clinical trial data. Companies will publicly post their data request review process and the identity of the external scientists and healthcare professionals who participate in the scientific review board, including any existing relationships with external board members.

When requests are granted, companies will share information to the extent permissible under informed consent forms and other legal requirements (e.g., privacy authorizations under the Health Insurance Portability and Accountability Act (HIPAA), contractual obligations). To protect patient privacy, companies will anonymize patient-level data before sharing it, and they will not provide access if there is a reasonable
likelihood that individual patients could be re-identified. Where legal restrictions prevent data sharing, the company will provide summary information to the researchers if possible.

Researchers will be encouraged to publish their findings, but they must agree not to: (1) attempt to re-identify subjects; (2) use the data for purposes not described in the proposal; or (3) transfer the data to parties not listed in the proposal. Companies also may require that researchers use the data for non-commercial purposes only and may refuse to grant data sharing requests from commercial competitors.

2. **Enhancing Access to Clinical Study Reports (CSRs).** Companies have also committed to enhance public access to clinical trial information. Within a reasonable time after approval of a new medicine or indication in the U.S. and EU, companies will make publicly available, at minimum, a synopsis of CSRs for clinical trials in patients submitted to U.S. and EU regulatory authorities, after appropriate redaction to protect patient privacy, publication rights, and intellectual property, including trade secret and confidential commercial information.

Companies will evaluate requests for *full* CSRs (including the patient- and study-level data) and share them with researchers under the terms of commitment 1. This commitment applies to CSRs filed with regulators on or after January 1, 2014.

3. **Sharing Clinical Trial Results with Clinical Trial Participants.** To inform patients about the clinical trials in which they participate, companies will work with regulators to adopt mechanisms for providing factual summaries of clinical trial results to research participants.
4. **Certifying Procedures for Sharing Clinical Trial Information.** Companies following the Principles will certify, on a publicly available web site, that they have established policies and procedures to implement the above data sharing commitment.

5. **Reaffirming Commitments to Publish Clinical Trial Results.** Companies will consider publishing all company-sponsored clinical trials in the scientific literature, irrespective of whether the results are positive or negative. At a minimum, results from all phase 3 clinical trials and any other clinical trials of significant medical importance (including trials from discontinued development programs) will be submitted for publication.

   These commitments build on prior PhRMA efforts to increase transparency of clinical trial information. For example, in 2002, PhRMA issued its Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results, and we have periodically updated these practices to expand the universe of publicly available clinical trial information. The current practices reflect our members’ commitments to, among other things: (1) timely register, on a public website, all interventional clinical trials in patients; and (2) timely post results information from these trials after approval or after research programs are discontinued.

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**III. Company Data Sharing Commitments Complement Existing Transparency Requirements**

Companies’ recent data sharing commitments complement Congress’s steps to increase transparency of clinical trial information while preserving incentives for innovation. In 2007, Congress expanded public access to information about ongoing

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and completed clinical trials.\textsuperscript{8} The FDA Amendments Act (FDAAA) required sponsors’ submission and posting of key information about ongoing clinical trials as well as certain clinical trial results and adverse event information.\textsuperscript{9} Presently, basic results information for applicable clinical trials, including primary and secondary outcomes and tabular summaries of the number and frequency of serious and common adverse events must be posted.\textsuperscript{10} FDAAA directed the Secretary of HHS to issue regulations that expand the results database,\textsuperscript{11} and we look forward to the eventual release of the proposed and final rules necessary for HHS to continue implementation of FDAAA.

FDAAA also requires FDA to publish “action packages” describing the bases for approval of new medicines.\textsuperscript{12} FDA must post a “summary review,” which describes the conclusions of all reviewing disciplines, any major disagreements, and their resolution shortly after approval.\textsuperscript{13} FDA subsequently must disclose its review documents and the Division Director and Office Director’s decision document for the medicine.\textsuperscript{14}

In enacting these provisions, Congress balanced the public interest in increasing transparency with the need to preserve incentives for innovation by private investment. Congress provided that “nothing” in the clinical trials database provision or the Freedom of Information Act (FOIA) “shall require the Secretary to publicly disclose, by any means other than the registry and results data bank”: (1) information submitted under the clinical trials database provisions or “information of the same general nature as (or integrally associated with)” it; and (2) information that is “not otherwise publicly

\textsuperscript{8} Public Health Service Act (PHSA) § 402(j).
\textsuperscript{9} Id. § 402(j)(2)(C)(ii) & (3).
\textsuperscript{10} Id. § 402(j)(3)(C), (E), (G), (I)(iii).
\textsuperscript{11} Id. § 402(j)(3)(D).
\textsuperscript{12} FDAAA § 916, 121 Stat. at 958-960 (adding new section 505(l)(2) of the FDCA).
\textsuperscript{13} FDCA § 505(l)(2)(B).
\textsuperscript{14} Id. § 505(l)(2)(A) & (C).
available, including because it is protected from disclosure under [the FOIA].” 15

Similarly, Congress clarified that the action package requirement does not authorize disclosure of “any trade secret [or] confidential commercial or financial information.” 16

These provisions thus reflect a careful balance between competing objectives.

PhRMA and its members supported passage of FDAAA, including the requirement for HHS to expand the results database through rulemaking. FDA has played a key role in implementation efforts, and PhRMA supports FDA’s and NIH’s work to enhance transparency in this congressionally endorsed manner.

Conclusion

In conclusion, PhRMA commends the Committee for its continued work in helping to ensure that clinical trial data are shared responsibly. PhRMA and its members have committed to sharing data in a way that aims to protect patient privacy, the integrity of regulatory decision-making, and incentives necessary for companies to make enormous long-term investments in medical research. We believe that a responsible approach must balance the expected benefits against the risks to patients and innovation. We look forward to continuing to work with other stakeholders to ensure that research from all sponsors, including academia and the government, may be shared in a responsible way.

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15 PHSA § 402(j)(6).
16 FDCA § 505(l)(2)(E).
Appendix A
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

Companies routinely publish their clinical research, collaborate with academic researchers, and share clinical trial information on public web sites at the time of patient recruitment, after new drug approval, and when investigational research programs have been discontinued.

Biopharmaceutical companies will apply these Principles for Responsible Clinical Trial Data Sharing as a common baseline on a voluntary basis, and we encourage all medical researchers, including those in academia and in the government, to promote medical and scientific advancement by adopting and implementing the following commitments:

1. Enhancing Data Sharing with Researchers

Biopharmaceutical companies commit to sharing upon request from qualified scientific and medical researchers patient-level clinical trial data, study-level clinical trial data, and protocols from clinical trials in patients for medicines and indications approved in the United States (US) and the European Union (EU) as necessary for conducting legitimate research. Companies will implement a system to receive and review research proposals and provide applicable data and protocols to help facilitate such scientific and medical research.

Each company will establish a scientific review board that will include scientists and/or healthcare professionals who are not employees of the company. Members of the scientific review boards will participate in the review of data requests to determine whether they meet the criteria described below regarding the qualifications of the requestor and the legitimacy of the research purpose, unless a company makes an initial determination on its own to share applicable clinical trial data. Companies will publicly post their data request review process and the identity of the external scientists and healthcare professionals who participate in the scientific review board, including any existing relationships with external board members.

Companies will provide access to patient-level data and other clinical trial information consistent with the principle of safeguarding patient privacy; patients’ informed consent provided in relation to their participation in the clinical trial will be respected. Any patient-level data that is shared will be anonymized to protect personally identifiable information. Companies will not be required to provide access to patient-level data, if there is a reasonable likelihood that individual patients could be re-identified. In addition, clinical data, in some cases, have been collected subject to contractual or consent provisions that prohibit transfer to third parties. Such restrictions
may preclude granting access under these Principles. Where co-development agreements or other legal restrictions prevent companies from sharing particular data, companies will work with qualified requestors to provide summary information where possible.

Data requestors will be required to submit a research proposal to document the legitimacy of the research question and the qualifications of the requestor. Research proposals should include, and will be evaluated against the following: a description of the data being requested, including the hypothesis to be tested; the rationale for the proposed research; the analysis plan; a publication and posting plan; qualifications and experience of the proposed research team; a description of any potential conflicts of interest, including potential competitive use of the data; and the source of any research funding.

Researchers who are provided access to company data will be encouraged and expected to publish the results of their analysis. Researchers must agree not to transfer the shared data or information to parties not identified in the research proposal, use the data for purposes not contained in the research proposal, or seek to re-identify research participants.

2. Enhancing Public Access to Clinical Study Information

In order to help patients and healthcare professionals understand the results of clinical trials and the evidence used to approve a new medicine, following approval of a new medicine or new indication for an approved medicine in the US and EU, biopharmaceutical companies will make publicly available, at a minimum, the synopses of clinical study reports (CSRs) for clinical trials in patients submitted to the Food and Drug Administration (FDA), European Medicines Agency (EMA), or national competent authorities of EU Member States. Companies will make this information available consistent with the need to protect patient privacy, publication rights, and confidential commercial information through appropriate redaction. In addition, companies will evaluate requests for full CSRs, including patient-level and study-level data, and share them under the terms of commitment 1 above. Companies will make available CSR synopses filed with regulators on or after January 1, 2014; such CSR synopses will be made available within a reasonable period of time after approval of the product and indication.

3. Sharing Results with Patients Who Participate in Clinical Trials

In order to help inform and educate patients about the clinical trials in which they participate, biopharmaceutical companies will work with regulators to adopt mechanisms for providing a factual summary of clinical trial results and make the summaries available to research participants.

4. Certifying Procedures for Sharing Clinical Trial Information

Companies following these Principles for Responsible Clinical Trial Data Sharing will certify on a publicly available web site that they have established policies and procedures to implement these data sharing commitments.

5. Reaffirming Commitments to Publish Clinical Trial Results

All company-sponsored clinical trials should be considered for publication in the scientific literature irrespective of whether the results of the sponsors’ clinical trials are positive or negative. At a minimum, results from all phase 3 clinical trials and any clinical trial results of significant medical importance should be submitted for publication. This commitment also pertains to investigational medicines whose development programs have been discontinued.

Implementation of these commitments will begin on January 1, 2014.
Q What type of information are biopharmaceutical companies prepared to share with qualified medical and scientific researchers under commitment 1?

A The biopharmaceutical industry is committing to sharing with qualified medical and scientific researchers patient-level data, study level data, and clinical study designs and protocols.

Patient-level data refer to 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. Such information has been gathered and recorded on case report forms (CRFs), or captured electronically and inputted into electronic databases, where it can be readily organized into patient-level listings and datasets. This information is created through what the Institute of Medicine (IOM) has described as a process by which data in a clinical study originate with CRFs, either handwritten or electronic, then go through several stages of auditing, queries, and refinement by original investigators and study staff to resolve ambiguities, and then ultimately yield “individual participant data.”

Study-level data consist of patient-level data that have been amalgamated, compiled and tabulated, manipulated, stratified, 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. Examples would include a table that presents cross-patient data on baseline patient characteristics (demographic and disease-related), patient disposition (i.e., numbers/percentages of patients who completed or discontinued the trial), endpoints (primary, secondary, and other), study drug exposure, adverse events, vital signs, and laboratory and other safety measures provided for the overall study population, and by subgroups.

Clinical study design information and protocols direct investigators how to run a particular study. Protocols give instructions to the investigators on, for example, what drug to give and when, what study measurements to take and when and how to record them, and how to treat and record adverse events.

Q What is the rationale for providing the synopsis of CSRs in commitment 2?

A Given the volume of data contained in regulatory submissions – often running to millions of pages – companies commit to publishing a synopsis after marketing approval in the US, EU, or member states. The synopsis will provide patients and their physicians with enhanced information about the results of clinical trials and the evidence used to approve a new medicine. The synopsis is a part of the CSR and is reviewed by the FDA and EMA as part of their approval. In order to accelerate research and advance scientific understanding, companies will also evaluate requests for full CSRs, including patient-level and study-level data, and share them under the terms of commitment 1.

In addition to providing the synopsis, some companies may choose voluntarily to provide to the public additional parts of CSRs redacted to protect patient privacy and confidential commercial information.
Q Why may it be necessary to limit the availability of patient-level data for clinical trials conducted involving patients whose data are likely to be re-identified?

A Protecting the privacy of patients who participate in clinical trials is a critical obligation of biopharmaceutical companies that sponsor and conduct medical research. It may be possible even for "anonymized" patient-level data to be re-identified using modern data mining techniques. For this reason, companies generally withhold patient-level information from disclosure when there is a reasonable possibility that patient privacy could be jeopardized. The risk of "re-identification" is significantly higher when the number of patients is small, such as is typically the case for trials involving patients with rare diseases, which may include as few as 25 or fewer patients.

Q Under commitment 1, are companies committing to share patient-level data and other proprietary information with competitors?

A No. Discovering and developing new medicines is a long, complex, and costly process. For every 5,000 to 10,000 experimental compounds considered, typically only one will gain FDA approval, after 10 to 15 years of research and development costing an average of $1.2 billion, based on a 2007 study. The few successes must make up for the many failures. In fact, only two out of every 10 medicines will recoup the money spent on their development.

Biopharmaceutical companies are dedicated to fostering a sustainable research ecosystem that protects the ability of companies to make extremely costly investments to discover and develop new medicines. One of the risks to innovation is disclosure to competitors of companies' trade secrets and proprietary information that could allow others to "free ride" off of the substantial investments of innovators. Such an environment will not foster the ability of companies to make decades-long investments in new medical technology. Therefore, in a sustainable research ecosystem, companies must be certain that their proprietary information will remain secure from disclosure to competitors. That is why commitment 1 calls for a company to share patient-level data and other confidential commercial information — which could be used to help gain approval of a competing medicine — only for legitimate scientific and medical research. Commitment 1 reflects these concerns by allowing companies to consider requests for release of clinical information in light of potential conflicts of interest, including any potential competitive use of the data.

Under commitment 1, companies will evaluate, among other things, whether the research proposed has a legitimate scientific or medical purpose, including whether there is any potential conflict of interest between the data requestor and the company or competitive use of the data. In the latter case, it may be assumed that the data requestor may intend to use the company's patient-level data or other information to help gain approval of a potentially competing medicine. While companies may enter into agreements to co-develop medical products, these data sharing Principles are not intended to allow free-riding or degradation of incentives for companies to invest in biomedical research. Accordingly, it would be appropriate under commitment 1 for companies to refuse to share proprietary information with their competitors.

Q How will companies determine who can receive patient level data or other proprietary information?

A Each company will implement a system for reviewing research proposals and the credentials of requesting researchers to determine that the proposed research is bona fide. Companies may choose to implement these systems individually or with centralized scientific review boards. Among the considerations for protecting patient privacy are the research participants' informed consent and other legal permissions, such as privacy authorizations (e.g., HIPAA in the United States) and/or data use agreements. With respect to these commitments to patients, any patient-level data that can be shared will, therefore, be "anonymized" in accordance with applicable legal requirements to protect personally identifiable information. Companies will not provide access to patient-level data when there is a reasonable likelihood that individual patients could be re-identified. In addition, where co-development...
agreements or other legal restrictions prevent companies from sharing particular data, companies will work with qualified requestors to provide summary information if feasible.

Q Will there be any other restrictions on use of data provided under commitment 1?
A Each company will determine the best method for safeguarding the privacy of patients and ensuring that access to patient-level data does not jeopardize incentives for future investment in biomedical research. Commitment 1 requires that data requestors must agree not to transfer shared data to parties not identified in the research proposal, use the data for purposes not contained in the research proposal, or seek to re-identify research participants. Companies may also require that the data are only used for non-commercial purposes. Additional conditions may include granting access to the data only on a company’s information system and/or requiring that data requestors notify the company of any safety finding that may be reportable to regulatory authorities or of other significant results.

Q Other than patient privacy information, what type of information could be withheld from CSR information provided to the public under commitment 2?
A In order to maintain incentives for future investment in biomedical research, individual companies may choose at their discretion to withhold from public access to CSRs various business and analytical methods; manufacturing and pre-clinical information or other confidential commercial information; any information not directly related to the conduct of the study or that could jeopardize intellectual property rights; or information that the company has no legal right to share (e.g., due to an existing co-development agreement).

Information withheld from public access to CSRs may nevertheless be available to qualified researchers under the terms of commitment 1.

Q If a company chooses, may it share more clinical trial information than is described in these commitments?
A Yes. Companies will make their own determinations regarding how to implement these commitments and whether to exceed these common commitments to responsible data sharing. For example, companies may choose to provide voluntarily to members of the public the main body of CSRs redacted to protect patient privacy or confidential commercial information.

1 Institute of Medicine, Sharing Clinical Research Data: A Workshop Summary 10 (2013).

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