Developing and Submitting Proposed Draft Guidance Relating to Patient Experience Data

Guidance for Industry and Other Stakeholders

DRAFT GUIDANCE

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For questions regarding this draft document, contact (CDER) Meghana Chalasani at 240-402-6525 or (CBER) Office of Communication, Outreach and Development, 800-835-4709 or 240-402-8010.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

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Guidance for Industry and Other Stakeholders[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

This guidance provides information on how a person can submit a proposed draft guidance relating to patient experience data for consideration by FDA. This guidance is intended to assist stakeholders seeking to develop and submit such proposed draft guidance to the Agency. In addition, FDA recognizes that stakeholders may have other information on patient experience data that they would like to share with FDA outside of the guidance process and thus provides information on other ways stakeholders can advance drug development by sharing patient experience data. Section 3002(c)(5) of the 21st Century Cures Act (Cures Act) directs FDA to issue guidance on how a person seeking to develop and submit a proposed draft guidance relating to patient experience data for consideration by FDA may submit such proposed draft guidance to the Agency.[2]

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

Under Section 569C(c) of the Federal Food, Drug, and Cosmetic Act (as amended by the Cures Act), patient experience data "includes data that (1) are collected by any persons (including patients, family members, and caregivers of patients, patient advocacy organizations, disease research foundations, researchers, and drug manufacturers); and (2) are intended to provide information about patients' experiences with a disease or condition, including (A) the impact (including physical and psychosocial impacts) of such disease or condition, or a related therapy

[1] This guidance has been prepared by the Office of the Center Director and the Office of Regulatory Policy in the Center for Drug Evaluation and Research (CDER), in cooperation with the Center for Biologics Evaluation and Research (CBER), at the Food and Drug Administration.

[2] See 21st Century Cures Act: https://www.congress.gov/114/plaws/publ255/PLAW-114publ255.pdf.

or clinical investigation on patients' lives; and (B) patient preferences with respect to treatment of such disease or condition."

Patient experience data can capture patients' experiences, perspectives, needs, and priorities related to (but not limited to):

- the symptoms of their condition and its natural history;
- the impact of the condition on their functioning and quality of life;
- their experience with treatments;
- input on which outcomes are important to them;
- patient preferences for outcomes and treatments; and
- the relative importance of any issue as defined by patients.[3]

Throughout the medical product lifecycle, patient perspectives may be valuable in addressing specific topics and questions. For instance, patient input on the therapeutic context (e.g., debilitating or most bothersome symptoms, disease impacts that matter most to patients, how well current treatment options help manage the condition) can be helpful at any stage of development.

Patient perspectives on clinical endpoints in clinical trials and clinical outcomes can inform stages of development from discovery through premarket review. This includes discussions on how well the most commonly studied endpoints in clinical trials align with outcomes or aspects of disease that matter most to patients, or whether patients' chief complaints about their condition are captured in clinical trials. During the design and conduct of a clinical trial, patient input can be gathered on: how patients excluded from clinical trials can be included in future trials, difficulties and challenges patients may be facing in participating in clinical trials, and various measures that may be taken to increase the likelihood of patient enrollment and retention in a trial.

As medical product development moves into premarket review and then the postmarket setting, it may be informative to collect patient input on benefits and risks and better understand attitudes toward or tolerance of potential medical product risks and how therapy side effects vary by subpopulation. Once a product is on the market, it is then helpful to understand whether the approved labeling is clearly communicating the information that patients need to safely and effectively use the product and whether there are challenges to adherence with prescribed therapies.

Patient experience data should be collected and analyzed in a methodologically sound and fit-for-purpose manner. There are several options for contributing patient experience data to the medical product development and regulatory decision-making process. One option is for stakeholders to submit proposed recommendations and considerations informed by patient experience data in the form of a proposed draft guidance.[4] Proposed draft guidance relating to

[3] See Patient-Focused Drug Development Glossary: https://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm610317.htm.

[4] See 21 CFR 10.115(f)(3).

patient experience data that is developed and submitted by external stakeholders can be helpful in bringing the patient's perspective into medical product development and regulatory decision-making. A stakeholder-submitted proposed draft guidance may be used to inform FDA's decision-making and future guidance development work, if applicable.

Under FDA's Good Guidance Practices regulations, FDA guidance documents describe the Agency's interpretation of or policy on a regulatory issue and are prepared for use by FDA staff, applicants/sponsors, and the public.[5] FDA guidance documents do not establish legally enforceable rights or responsibilities and do not legally bind the public or FDA.[6] When issuing a Level 1 guidance, FDA will typically issue draft guidance, request public comment, and following review of received comments, finalize the guidance document.[7] FDA may also revise existing guidance if warranted, typically using the same process.

Submitting proposed draft guidance for FDA's consideration is not the only option for contributing patient experience data. Patients, caregivers, patient and disease advocacy groups, and other stakeholders with knowledge of or access to the patient community, may be well-positioned to also make broader contributions to advance medical product development.

Recognizing that stakeholders may be interested in pursuing other pathways to contribute patient experience data, this guidance addresses questions relating to both guidance development and other potential pathways for contributing patient experience data. The questions addressed in this guidance are as follows:

- Development and submission of proposed draft guidance relating to patient experience data:
  - What factors should stakeholders consider when planning and determining whether to develop a proposed draft guidance relating to patient experience data to submit to FDA?
  - How can stakeholders communicate with FDA that they plan to develop a proposed draft guidance relating to patient experience data?
  - What are some general considerations regarding format of the proposed draft guidance?
  - How should stakeholders submit proposed draft guidance to FDA?
  - What will happen after stakeholders submit the proposed draft guidance to FDA?
  - Can a stakeholder submit proposed revisions to an existing FDA guidance?
  - What are other ways for a stakeholder to participate and provide input on FDA policy and guidance development?

- Other opportunities for stakeholders:
  - What are other opportunities for stakeholders to help advance patient-focused drug development?
  - How can patient experience data inform medical product development and regulatory decision making?

[5] See 21 CFR 10.115(b).

[6] Although guidance documents generally reflect FDA's current thinking, FDA staff may depart from guidance documents with appropriate justification and supervisory concurrence. See 21 CFR 10.115(d).

[7] Procedures for issuing and commenting on FDA draft guidance documents may vary depending on the type of draft guidance issued. For specific information about FDA's Good Guidance Practices, see 21 CFR 10.115.

- What work products relating to patient experience may be developed by stakeholders?
- How can stakeholders submit other work products relating to patient experience data?

Resources for stakeholders relating to patient-focused drug development (e.g., decision tools, flow charts, templates) will be posted on FDA's CDER Patient-Focused Drug Development web page,[8] and updated as new resources are developed.

III. QUESTIONS AND ANSWERS

A. Development and Submission of Proposed Draft Guidance Relating to Patient Experience Data

1. What factors should stakeholders consider when planning and determining whether to develop a proposed draft guidance relating to patient experience data to submit to FDA?

Before initiating development of a proposed draft guidance, stakeholders should consider the following:

a. Is there a stage in a medical product lifecycle that could be particularly informed by patient experience data for a given disease area (e.g., in discovery phase, to identify appropriate unmet needs to suggest potential drug targets; during development to suggest appropriate disease populations, enrollment criteria for trials, and important trial endpoints; late stage in development to understand acceptable benefit-risk balance and treatment burden; and post-approval to understand acceptable safety)?

b. Is the development of a proposed draft guidance the best way to address an identified need in a given disease area?

FDA guidance documents cover a range of topics, including: (1) clinical guidance that may provide more general treatment of issues related to drug development for a given disease and with broad discussion of subpopulation issues; and (2) methodological guidance that may provide general treatment of methodological issues and cover a range of research trial settings, patient populations, cultural contexts, and sociodemographic considerations.

It may be appropriate for stakeholders to develop a proposed draft guidance if:

- FDA has issued a clinical guidance in a given disease area, but the guidance does not address considerations and/or examples for a specific subpopulation. A stakeholder may want to provide subpopulation-specific considerations,

[8] See CDER Patient-Focused Drug Development Homepage: https://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm579400.htm.

examples, and/or recommendations related to the disease area discussed in the FDA guidance.

- FDA has issued a methodological guidance (e.g., adaptive clinical trial designs) that is applicable to a range of disease areas and patient populations, but the guidance does not provide specific considerations or examples of how the methods can be applied or adapted for a specific disease area and/or subpopulation. A stakeholder may want to provide disease- or subpopulation-specific considerations, examples, and/or recommendations related to the methods discussed in the FDA guidance.

- FDA has not issued a clinical guidance in a given disease area, but there appears to be a need for a disease-specific guidance to address topics related to patient experience data (e.g., clinical outcome assessments, endpoints, clinical trial considerations). Please note that CDER and CBER each publish on FDA's website a list of guidance topics that the respective Center is considering for development during the current calendar year.

c. Are resources, expertise, and stakeholder capacity available to collect any relevant patient experience data, conduct required analysis, and further develop a proposed draft guidance? Would the available resources be more suitable to focus on other efforts (e.g., those discussed in Section II, Other Opportunities for Stakeholders)?

FDA encourages contacting FDA staff early to discuss patient experience data that may be useful to collect and submit to the FDA. Please refer to the series of FDA Patient-Focused Drug Development guidances before collecting patient experience data.[9]

d. If patient experience data has been collected and analyzed, is it suitable to provide recommendations or considerations to include in a proposed draft guidance? If not, stakeholders should consider other opportunities to share patient experience data (see Section II, Other Opportunities for Stakeholders).

2. How can stakeholders communicate with FDA that they plan to develop a proposed draft guidance relating to patient experience data?

Stakeholders are not required to communicate with FDA in advance of submitting a proposed draft guidance. However, when developing proposed content for disease- and indication-specific recommendations for FDA's consideration, it may be helpful (for FDA awareness) to provide FDA with a brief summary of the expected content, along with a projected timeframe for submission and a point of contact for potential follow-up. Ideally, these summaries will be brief (2-3 pages at maximum) and should be sent only to PED-

[9] See FDA draft guidance for industry and other stakeholders, *Patient-Focused Drug Development: Collecting Comprehensive and Representative Input* (June 2018). When final, this guidance will represent FDA's current thinking on this topic. For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

ProposedGuidanceSummary@fda.hhs.gov. No other documents or inquiries should be sent to that email address. The email title should reflect that the summary is a "Development Summary for Anticipated Proposed Draft Guidance" and indicate the subject matter (e.g., disease area) for the anticipated proposed draft guidance. After receipt by the Agency, the summaries will be directed internally to appropriate points of contact for awareness and consideration. While FDA does not intend to issue acknowledgement letters or other communications in response to these summaries as a matter of course, the Agency may reach out to points of contact identified should the Agency believe follow-up would be useful.

3. What are some general considerations regarding the format of a proposed draft guidance?

A proposed draft guidance should be formatted so that it provides clear and concise recommendations for FDA to consider should FDA develop a guidance on the topic, and should not give the impression that it is an FDA-drafted document. A proposed draft guidance should:

a. Address one or two topics relevant to a specific disease area drug development plan.

b. Be written from the stakeholder's perspective, not as FDA. For example, language such as "FDA suggests," "FDA encourages," and "FDA recommends" should not be used. Instead, FDA recommends language such as "The available patient experience data suggests that patients seek X" or "We recommend that sponsors consider."

c. Include a unique title page. The proposed draft guidance should not follow FDA's visual identity program or mirror the formatting style of FDA guidance documents.

d. Refrain from making any statement that indicates, implies, or suggests that FDA has endorsed the document, including by use of the FDA logo.

e. Be succinct and generally no more than 5 pages.

f. Include an introduction clearly stating the purpose of the proposed draft guidance; provide high-level background that includes a brief description of the disease, patient population, severity of the condition, available treatment options, and topics or issues to be addressed in the document; and propose considerations and recommendations on the topics or issues relevant to the purpose of the proposed draft guidance. Please refer to examples of FDA's short disease-specific bulleted guidance documents (e.g., (1) *Inborn Errors of Metabolism That Use Dietary Management: Considerations for Optimizing and Standardizing Diet in Clinical Trials for Drug Product Development*, (2) *Hypertension: Conducting Studies of Drugs to Treat Patients on a Background of Multiple Antihypertensive Drugs*, and (3) *Pediatric HIV Infection: Drug Development for Treatment*) and consider a similar format.

g. If applicable, include specific examples. Examples could be related to a specified subpopulation or special issues defined by factors such as patient age, disease severity, co-morbidities, or other concerns. They might also relate to how specific methods recommended in existing FDA guidance would or would not be applied in specific trial settings for specified patient subpopulations, including variations in economic and cultural context, language ability, literacy, numeracy, mobility, or age group. Stakeholders may also propose examples of alternative methods that may be most applicable.

h. Include a study report and protocol when submitting methodologically collected patient experience data as supporting information with a proposed draft guidance. If applicable, also include additional information such as the primary data capture. For additional guidance on submission of patient experience data, please reference FDA draft guidance on Patient-Focused Drug Development: Collecting Comprehensive and Representative Input.[10]

4. How should stakeholders submit proposed draft guidance to FDA?

As specified in FDA's Good Guidance Practices regulations,[11] drafts of proposed guidance documents should be marked "Guidance Document Submission," and submitted to:

Division of Dockets Management (HFA-305),
5630 Fishers Lane, Rm. 1061,
Rockville, MD 20852

Stakeholders may also submit a proposed draft guidance electronically via www.regulations.gov under the shell docket 2013-FDA-S-0613. Instructions for filing a proposed draft guidance electronically are available in that shell docket and on FDA's guidances web page.[12]

5. What will happen after stakeholders submit the proposed draft guidance to FDA?

For stakeholders interested in submitting a proposed draft guidance, FDA's Division of Dockets Management will open a new docket for each proposed draft guidance document submission and will send a letter to acknowledge receipt of the proposed draft guidance. The proposed draft guidance document will be available to the public. After receiving the proposed guidance document submission from the Division of Dockets Management, FDA's CDER or CBER will ensure it is sent to the relevant office(s) and/or division(s) within each Center.

Submission of a proposed draft guidance to FDA does not mean that FDA will publish its own draft guidance on the topic(s) identified. FDA has its own process for developing guidance based

[10] See FDA draft guidance *Patient-Focused Drug Development: Collecting Comprehensive and Representative Input*.
[11] See 21 CFR 10.115.
[12] See FDA's Instructions for Submitting Drafts of Proposed Guidance Documents Electronically available on FDA's web page at: https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm601464.htm.

on several factors including the state of the science in a given area, policy priorities, and Agency resources. The stakeholder-submitted proposed draft guidance can be used to inform FDA's thinking and future guidance development work, if applicable.

6. Can a stakeholder submit proposed revisions to an existing FDA guidance?

Under FDA's Good Guidance Practice regulations, stakeholders can provide comments on a guidance document at any time. They may also suggest that FDA revise or withdraw an existing guidance document.[13] The suggestion should address why the guidance document should be revised or withdrawn and, if applicable, how it should be revised. The suggestion should be submitted as a comment to the public docket assigned to that specific guidance. To find an assigned public docket, please visit www.regulations.gov and search for the specific guidance.

7. What are other ways for a stakeholder to participate and provide input on FDA policy and guidance development?

There are other opportunities for stakeholders to provide input on FDA policy and guidance development, such as participating in FDA-led meetings. Stakeholders are encouraged to attend FDA-led public meetings on policy development, patient-focused drug development, or technical issues in a given disease area. In addition to participating in meetings, stakeholders can submit written comments to the public docket that is assigned to each meeting.

B. Other Opportunities for Stakeholders

Stakeholders, including patient and disease advocacy groups, may be well positioned to make contributions to advance the understanding of disease burden, progression, treatment burden, challenges to clinical trial participation, and other issues and policy considerations from the perspective of patients and caregivers. This work can be pursued by stakeholders on their own, independent of FDA involvement.

1. What are other opportunities for stakeholders to help advance patient-focused drug development?

There are several other opportunities stakeholders may wish to pursue depending on their particular capabilities, expertise, and priorities. Other areas of opportunity may include:

a. Developing a patient registry: The purposes for patient registries can range widely, including use in recruiting patients for clinical trials; providing information on a given disease area; developing therapeutics; learning about behavior patterns and their association with disease development; and developing research hypotheses. Patient registries can also be used to monitor outcomes and study best practices in care or treatment.[14]

[13] See 21 CFR 10.115(f)(4).

[14] See Engaging Patients in Information Sharing and Data Collection: The Role of Patient-Powered Registries and Research Networks [Internet]: https://www.ncbi.nlm.nih.gov/books/NBK164514/.

b. Conducting natural history studies: Stakeholders may collaboratively develop and conduct natural history studies. Natural history studies track the course of disease over time, identifying demographic, genetic, environmental, and other variables that correlate with its development and outcomes in the absence of treatment. These studies can inform the basis for recruiting and retaining patients in clinical trials.

Stakeholders, including investigators from industry, academia, patient and disease advocacy groups, and government, may also request a Critical Path Innovation Meeting with FDA to discuss topics regarding natural history study designs and implementation, biomarkers in the early phase of development, clinical outcome assessments in the early phase of development, innovative conceptual approaches to clinical trial design and analysis, and plans to collect patient experience data.[15]

c. Coordinating work among patient groups and other stakeholders: It is helpful for patient groups to align efforts to advance work in a disease area. This can help ensure that patient groups avoid duplicative efforts and help maximize the use of resources and valuable patient and staff time.

Stakeholders may also wish to establish public-private partnerships or consortia to bring multiple stakeholders together, including FDA, to address issues that are beyond the capacity and resources of a single organization.[16]

d. Communicating, educating, and conducting outreach: Stakeholders, particularly patient groups, may be well positioned to communicate and conduct outreach with the patient community through sources such as emails, newsletters, and social media. This outreach will help ensure that communities are aware of continuing work in the disease area, along with opportunities to engage with other stakeholders.

Patient groups may be well positioned to help develop and conduct trainings to educate communities on a given disease and medical product development for that disease. Topics for trainings may include types of research and testing needed to develop and manufacture safe and effective treatments, timeframes required for development, phases of clinical development, importance of clinical trials, and where to access clinical trials.

e. Convening meetings: Stakeholders can convene meetings to advance discussion on topics related to medical product development for a given disease. For

[15] See FDA Critical Path Innovation Meeting website: https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugInnovation/ucm395888.htm.

[16] For information about CDER's policy and procedures governing its staff participation in public private partnership and consortia, see CDER Manual of Policies and Procedures on CDER Staff Participation in Public-Private Partnerships and Consortia: https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/UCM532571.pdf.

example, stakeholders can host meetings on scientific or technical issues to discuss challenges or opportunities in a given disease area related to enhancing a clinical development program. This can be an opportunity to convene experts from patient and disease advocacy groups, federal agencies, industry, academia, and healthcare institutions to discuss specific scientific or technical issues that may need further structuring, identification of areas for further research, or enhanced data collection.

f. Collecting patient experience data: Patient input can help inform the therapeutic context for regulatory review. Patient input can also provide a direct source of evidence regarding the benefits and risks of a medical product, if methodologically-sound data collection tools are developed and used within clinical trials of an investigational therapy.

In the early stages of drug development (e.g., discovery), patient and disease advocacy groups may conduct an externally-led Patient-Focused Drug Development meeting or focus group to gather patients' perspectives on disease and treatment burden. [17] The information and perspectives obtained in these meetings can be used to develop meeting reports or other work products summarizing what was heard.

Stakeholders, in collaboration with appropriate methodologists, can conduct methodologically-sound surveys to collect representative input on patients' experiences living with their disease, using available treatments, accessing and participating in clinical trials, and weighing acceptable levels of benefits and risks.

Stakeholders may also want to consider collaborating with one or more sponsors to collect patient input on a given disease, including patient input on the significant symptoms of the given disease, currently available treatments for the given disease, or other types of patient experience data. Stakeholders may also want to consider sharing their independently collected patient experience data with sponsors for potential use in decision-making.

For methodological considerations when collecting patient experience data, please refer to the series of methodological Patient-Focused Drug Development guidances being developed by FDA.[18]

2. *How can patient experience data inform medical product development and regulatory decision making?*

[17] See FDA Externally-led Patient-Focused Drug Development Meetings website: https://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm453856.htm.

[18] See FDA Patient-Focused Drug Development Methodological Guidance Series for Enhancing the Incorporation of the Patient's Voice in Medical Product Development and Regulatory Decision Making: https://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm610279.htm.

Patient experience data that is collected and corresponding work products that are generated can serve as a valuable resource to multiple stakeholders throughout medical product development and decision-making, including FDA, other federal partners, industry, patient and disease advocacy groups, healthcare providers, and academic researchers. For a high-level overview of how patient experience data could enhance medical product development and decision-making, please see **Table 1.**

Table 1: How Patient Experience Data Could Enhance Medical Product Development and Decision Making

Type of Patient Experience Data	Type of Stakeholder		
	Patient Stakeholders*	**Medical Product Developers/Researchers**	**Regulators**
Patient registry or natural history study data	• Inform communications, education and outreach efforts for the patient community • Inform future research • Provide basis for recruitment in clinical trials	• Help identify biomarkers and clinical outcome measures that will show how well a patient responds to a treatment in clinical trials • Inform clinical trial design • Support clinical trial recruitment	• Enhance the understanding of the course of disease over time, identifying demographic, genetic, environmental, and other factors that correlate with its development and outcomes in the absence of treatment (or while on available therapies)
Study report or survey data on the therapeutic context (severity of condition and unmet medical need), including perspectives on disease background, severity of condition, and available treatment options	• Identify burden of disease and unmet medical needs that warrant further scientific discussion • Identify opportunities and gaps where further development and research may be needed • Identify considerations for clinical endpoints and clinically meaningful outcomes • Inform patients on possibilities to participate in development and validation of clinical trial endpoints and patient-reported outcomes	• Informs Target Product Profile • Identify clinical domains (e.g., most bothersome symptoms) of the condition that could be targeted for new treatment development • Identify how the condition may vary by sociodemographic factors, subgroups, culture, and disease severity • Inform the selection, development and modification of meaningful clinical endpoints and outcomes, and tools that measure what matter most to patients • Inform clinical trial design, including appropriate inclusion and exclusion criteria	• Inform FDA decision-making throughout medical product lifecycle • Enhance the understanding of the therapeutic context for benefit-risk assessments • Enhance understanding of meaningful endpoints and outcomes to patients to appropriately advise sponsors on a medical product development plan in early phases of development • Inform FDA guidance on disease-specific clinical, scientific and regulatory matters • Inform FDA assessments of medical product development programs
Clinical trial experience data, including perspectives on trial visits and assessments	• Help clinical trial participants better prepare for the trial, including the informed consent process • Inform patients on opportunities to participate in clinical trials and improve overall recruitment • Help individual decision making on whether to enroll in a trial	• Enhance recruitment and retention for clinical trials • Inform development of informed consent documents • Provide insight into clinical trial participant burden, including frequency and conduct of trial visits and assessments	• Enhance understanding of patient's experience with clinical trial design and inclusion/exclusion criteria to better advise sponsors
Patient input on benefits and risks	• Inform future research • Identify unmet medical needs that warrant further scientific discussion • Enhance the understanding of benefits and risks for patients	• Enhance the understanding of patient input on benefits and risks to inform benefit-risk assessment	• Enhance the understanding of patient input on benefits and risks to inform benefit-risk assessment

Type of Patient Experience Data	Type of Stakeholder		
	Patient Stakeholders*	**Medical Product Developers/Researchers**	**Regulators**
Perspectives on ways to communicate information to patients and prescribers	• Inform communications and education for the patient community to enhance shared decision-making between patients and prescribers	• Improve the overall communication of information to patients and prescribers	• Inform how to convey key information that helps facilitate patients' informed decision-making
* Patient stakeholders include patients, caregivers, and patient advocates. To provide standardized nomenclature and terminologies related to patient-focused medical product development, these terms are defined in FDA's Patient-Focused Drug Development Glossary.			

3. What work products relating to patient experience data may be developed by stakeholders?

A range of work products related to patient experience can be developed to provide helpful data and information to facilitate patient-focused drug development in a given disease area. Work products may include:

- Meeting reports summarizing patient perspectives on disease and treatment burden
- Methodologically-sound patient surveys
- White papers or peer-reviewed journal articles describing topics such as background on disease, and considerations for clinical trials in a given disease area
- Case examples to address disease-specific considerations related to medical product development
- Natural history study report
- Proposed draft guidance relating to patient experience data.

4. How can stakeholders submit work products relating to patient experience data?

Stakeholders who would like to share work products (e.g., meeting reports, surveys) with FDA may visit the FDA's External Resources and Information Related to Patient Experience web page.[19] This web page provides links to publicly available reports and resources relating to patient experience data. Key stakeholders including patient communities, patient advocates, researchers, drug developers, and federal agencies may find these materials useful. Please note that although FDA reviews the materials at these links before posting them to ensure that the materials are within the scope of the web page, FDA does not assess their scientific merit or compliance with applicable regulatory requirements. FDA's decision to post links to these materials does not reflect an endorsement of their authors, sponsors, or content.

Please visit the web page for more information regarding what types of resources may be included on this web page, how to submit a publicly available website link for this web page, and other general questions.

To submit proposed draft guidance documents, follow the process outlined in this guidance (See Section III.A, Development and Submission of Proposed Draft Guidance Relating to Patient Experience).

[19] See FDA's External Resources or Information Related to Patients' Experience web page: https://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm579132.htm.