PCORI HEALTH CARE HORIZON SCANNING SYSTEM

Horizon Scanning Protocol and Operations Manual

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A representative from PCORI served as a contracting officer’s technical representative and provided input during the implementation of the Horizon Scanning System. PCORI does not directly participate in horizon scanning or assessing leads or topics and did not provide opinions regarding the potential impact of interventions.

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None of the individuals compiling this information have any affiliations or financial involvement that conflict with the material presented in this report.

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Preface

The PCORI Health Care Horizon Scanning System (HCHSS) conducts horizon scanning of new and emerging health care technologies and innovations with high potential for disruption to the current standard of care to better inform patient-centered outcomes research investments at PCORI. The HCHSS provides PCORI with a systematic process to identify and monitor technologies and innovations in health care that are in PCORI’s priority areas of interest and to create an inventory of interventions that have the highest potential for disruption to the current standard of care in terms of patient outcomes, health disparities, care delivery, infrastructure, access, and/or costs. It is also a tool for the public to identify information on selected new health care technologies and interventions. Any investigator or funder of research can use the PCORI HCHSS to help select research topics.

The health care technologies and innovations of interest for horizon scanning are those that have yet to become part of established health care practices. These interventions are in late stages of research and development or very early phases of adoption, except in the case of new applications of already-diffused technologies. Consistent with the definitions of health care interventions provided by the National Academy of Medicine and the Federal Coordinating Council for Comparative Effectiveness Research, PCORI is interested—at present—primarily in innovations in drugs and biologics, medical devices, and procedures within its selected priority areas of interest for horizon scanning. PCORI may choose, upon future consideration, to expand its focus to include a wider range of interventions (eg, systems innovations).

Horizon scanning involves 2 processes. The first identifies and monitors new and evolving health care interventions that purportedly hold potential to diagnose, treat, or otherwise manage a disease or condition or to improve care delivery. The second analyzes the relevant health care context in which these new and evolving interventions would exist to understand their potential for disruption to the standard of care. The goal of the PCORI HCHSS is not to predict future utilization and costs of any health care intervention; rather, the reports are intended to help inform and guide planning and prioritization of research resources.

Horizon Scanning is an iterative process that relies on constant feedback to remain effective; therefore, a horizon scanning system must be dynamic and flexible in its design and approach. Although a system must be designed carefully at the outset, it also must not remain static as times and priorities change. Therefore, ECRI periodically reviews the PCORI HCHSS Horizon Scanning Protocol and Operations Manual and, based on the best available evidence and in coordination with PCORI, makes changes to the protocol to improve the system’s efficiency, output quality, and relevance.

We welcome comments on this document. Send comments by mail to William Lawrence, MD, MS, Patient-Centered Outcomes Research Institute, 1828 L St., NW, Suite 900, Washington, DC 20036, or by email to horizonscan@pcori.org.
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Introduction

Horizon scanning is a systematic process that serves as an early warning system to inform decision makers about possible future opportunities and threats. Health care horizon scanning identifies technologies, innovations, and trends with potential to cause future shifts or disruptions—positive or negative—in areas such as access to care, care delivery processes, care setting, costs of care, current treatment models or paradigms, health disparities, health care infrastructure, and patient health outcomes. Examples of horizon scanning targets include new (and new uses of existing) pharmaceuticals, medical devices, diagnostic tests and procedures, therapeutic interventions, rehabilitative interventions, mental and behavioral health interventions, health care delivery innovations, and public health and health promotion activities.

Health care horizon scanning has typically informed strategic planning activities. Public and private entities around the world have long used formal or informal health care horizon scanning programs for purposes including commercial planning, health services research prioritization, financial or operational planning, controlled diffusion of technologies, and provision of information to policymakers, purchasers, and health care providers.

For example, health systems have used horizon scanning data to inform their 5-year technology acquisition plans to better understand how innovations might affect or disrupt their clinical service lines. Third-party payers (health insurance companies and government payers) have used horizon scanning data to prepare coverage decisions. Some, such as the EuroScan horizon scanning system, might also inform decisions regarding conduct of primary or secondary research (eg, health technology assessment).

From December 2010 through December 2015, ECRI created and operated a national Healthcare Horizon Scanning System for the US Agency for Healthcare Research and Quality (AHRQ) to inform comparative effectiveness research investments made through AHRQ’s Effective Health Care Program. Before this initiative, no publicly available, comprehensive system existed for health care horizon scanning in the United States. AHRQ identified the following goals for its health care horizon scanning activities:

- Create and use transparent and clearly defined processes to identify and monitor novel interventions or new uses of existing interventions in health care that might address an unmet need.
- Develop and implement a transparent and clearly defined framework for identifying which interventions could have the highest potential impact on clinical care, the health care system, patient outcomes, and costs.
- Evaluate components of existing horizon scanning systems and their respective protocols to identify best practices and effective methods of horizon scanning.
The PCORI Health Care Horizon Scanning System builds on concepts and approaches developed for the AHRQ system. Initially, PCORI defined its project scope to focus on interventions with high potential for disruption in the United States in 5 priority areas: Alzheimer’s disease and other dementias, cancer, cardiovascular diseases, mental and behavioral health conditions, and rare diseases. In addition, the system captures high-level disruptive trends across all clinical areas, which may lead PCORI to expand the project scope to include other priority areas in the future.

This document outlines the basic protocol and decision processes used to scan for leads, select interventions and trends for monitoring, and identify interventions in each priority area and trends across all clinical areas with high potential to cause disruption to health care in the United States. An overview of these processes is shown in Figure 1.
Figure 1. PCORI Health Care Horizon Scanning System Process Overview

1. **BROAD SCANNING (ongoing):** Scanners conduct broad scanning and select leads for horizon scanning analysts to consider for potential topics and trends.

2. **LEAD REVIEW AND TOPIC/TREND IDENTIFICATION (ongoing):** Analysts review leads in assigned priority areas and collect basic information on topics and trends that appear to meet inclusion criteria for the Horizon Scanning System.

3. **TOPIC VETTING (ongoing):** An analyst may elect to send a topic through a vetting step to elicit expert opinion on the topic as an input into topic nomination process. Trends are not sent through this process.

4. **TOPIC AND TREND NOMINATION (monthly):** At Topic and Trend Nomination meetings, analysts present topics or trends to the Horizon Scanning Team to discuss and vote on whether the topics or trends should be included in the PCORI Health Care Horizon Scanning System.

5. **STATUS REPORT (4 times annually):** The Horizon Scanning team reviews all included topics and trends to update development status and other information (as needed), prepares the Status Report, and archives topics and trends that no longer meet inclusion criteria.

6. **TOPIC AND TREND PROFILE DEVELOPMENT (ongoing):** Included topics that have late-phase efficacy data undergo detailed searches by librarians; analysts prepare topic and trend profiles, which will be sent for stakeholder comment (below).

7. **STAKEHOLDER SURVEY PROCESS (ongoing):** Topic and trend profiles are sent for comment to stakeholders (clinicians, health systems experts, researchers, patients, patient representatives, caregivers) to gather diverse perspectives on each topic’s or trend’s potential for disruption.

8. **HIGH POTENTIAL DISRUPTION REPORT (twice annually):** Analysts review stakeholder ratings and comments received in the past 12 months; team convenes to determine which topics and trends stakeholders thought had high potential for disruption; team writes analysis of topics and trends selected for inclusion in the High Potential Disruption report.

9. **TOPIC MONITORING AND UPDATING (ongoing):** Analysts review active topics and trends to prioritize new and updated existing topic and trend profiles for next round of stakeholder comments; analysts recommend topics and trends for archive as appropriate.
PCORI Health Care Horizon Scanning System Process

In this section, we describe the overall process and discrete steps involved in creating, operating, and maintaining the PCORI Health Care Horizon Scanning System (HCHSS).

Operational Terms and Definitions

Although we use plain language whenever possible throughout this protocol, the technical nature of the horizon scanning process occasionally requires defining terms more narrowly than would be found in common usage. We define those terms below.

Intervention

An intervention is a particular drug, device, procedure, surgery, care delivery innovation, diagnostic, or treatment. When we refer to an intervention as such, we generally refer to the thing itself regardless of its specific context (ie, its specific use for a specific disease/condition).

Topic

A topic is a particular intervention, as defined above, within the specific context for its use. The context for its use requires defining the specific patient population, disease/condition and stage of the disease/condition, and the care delivery setting. Thus, a topic is the intervention for a specific population with a specific disease/condition and stage and intended purpose (eg, treatment, diagnosis, screening). Within the PCORI HCHSS, a particular intervention may be the subject of more than one topic because the intervention may be used, for example, for treating more than one disease/condition (eg, different cancers and stages of a cancer type) or patient population (eg, adults, children, infants).

Lead

A lead is a single piece of information from any source (eg, published trial, press release, news article, web page) that may contain information pertaining to one or more topics (see above) or disruptive trends (see below). Leads are identified during broad scanning activity (see Step 1 below) and reviewed to determine whether they contribute to or become a topic (see Step 2 below).

Priority Area

A priority area is a general clinical area of focus defined by PCORI for its HCHSS. For this project’s initial stage, PCORI has defined 5 priority areas: Alzheimer’s disease and other dementias, cancer, cardiovascular diseases, mental and behavioral health conditions, and rare diseases (ie, affecting fewer than 200 000 individuals in the United States).
Disruption

A *disruption* is a change or shift (positive or negative) in one or more key dimensions of health care in the United States, including, but not limited to, access to care, care setting, clinician and/or patient acceptance of the intervention, clinician and/or patient learning curve to use the intervention, costs of care, current treatment models/paradigms, disparities, health care delivery processes, infrastructure needs, and patient health outcomes. (We have listed these dimensions alphabetically to avoid implying a weighted order of priority.) Although *disruption* may refer to a shift in a single dimension, *overall disruption* considers shifts occurring across the health care spectrum. An example of a disruption across multiple dimensions is a new treatment for a genetic disorder that can virtually cure the disorder, which previously had no treatment options. This could affect the care delivery paradigm, possibly the infrastructure needed to deliver care, patient health outcomes, health disparities, and other parameters.

Disruptive Trend

A *disruptive trend* is a large, high-level disruption occurring across clinical areas or within a clinical area from a combination of factors that, taken together, create a paradigm shift. For example, the continued and rapid development of expert artificial intelligence systems in health care is a disruptive trend cutting across all clinical areas and is increasingly shifting paradigms and transforming processes of screening, diagnosis, and treatment. Another example of a disruptive trend within a single clinical area is the development of immunotherapies, such as CAR-T cell therapy, for various cancers.
Step 1. Broad Scanning

To identify potential topics, scanners (e.g., medical librarians, information specialists, research assistants) capture leads and funnel them to a team of horizon scanning analysts (i.e., PhD- and master’s-level scientists from medical or life sciences, health care research, and clinical fields). As related leads aggregate, analysts develop specific topics or trends (see Step 2. Leads Review and Topic and Trend Identification).

Scanning concentrates on the 5 priority areas specified by PCORI: Alzheimer’s disease and other dementias, cancer, cardiovascular diseases, mental and behavioral health, and rare diseases. In addition, broad scanning captures signals of high-level disruptive trends occurring across all clinical areas. Scanners access public and proprietary resources in the health, scientific, and business spheres to scan for new developments in all facets of health care–related topics (Table A.1). These include the following:

- ECRI’s research publications and the questions it receives from health systems, health plans, and other entities that use the organization’s services
- Aggregated news sources (e.g., PR Newswire health and science industries)
- News releases and conference proceedings from meetings of professional societies and other organizations (e.g., trade associations, industry associations)
- Repositories of peer reviewed journals (both general medical and specialty journals) and gray literature (e.g., government- and manufacturer-issued documents, health care and medical science trade publications and newsletters, other health care information published outside the peer reviewed journal literature) (Tables A.2 and A.3)

To ensure that scanners do not miss important signals, scanners initially review resources without employing a search strategy. When possible, distribution of publications is customized (e.g., Really Simple Syndication feeds) to send daily email updates and electronic tables of contents to scanners or to allow scanners to set automated alerts that will notify them when new content is available.

Specific resources, such as those listed in Table A.1, are assigned to individual scanners, who review new content regularly. Each scanner creates a schedule for scanning resources that do not offer automated alerts. These resources are reviewed daily, weekly, monthly, or quarterly depending on their publication schedule.

During broad scanning, several sets of questions inform scanners’ thinking about whether a lead appears to represent a novel, innovative, or relevant intervention and may disrupt one or more areas of health care, such as patient health, health care processes, delivery, cost, care setting, or disparities. The sets of questions considered help the team filter out interventions that are very similar to interventions already available and diffused and would likely not be disruptive.

Below we outline the questions we consider for drugs, biologics, devices, surgical procedures, mental and behavioral health interventions, and high-level disruptive trends. These questions reflect PCORI’s initial areas of focus, which PCORI may choose to expand in the future.

Questions Considered About Drugs, Biologics, and Devices

Is this a new molecular entity (drug), biologic, or device being developed for potential diffusion into the US health care system AND in late-phase (phase III or IV) clinical development or in phase II clinical development with orphan, breakthrough, or fast-track status
designation by the US Food and Drug Administration (FDA)? Consider the following when deciding to select:

1. Is it subject to approval under FDA’s Investigational New Drug, Biologics License Application, combination-product application, Investigational Device Exemption, Premarket Approval, or Humanitarian Device Exemption approval process? If so, select.
2. Is it a generic drug or a biosimilar? If so, do not select because these are very similar to or identical to existing drugs.
3. Is it subject to 510(k) clearance or De Novo pathway? If so, select only if it appears to represent some sort of disruptive innovation.
4. Is this a late-phase human clinical trial of either an apparent novel intervention or a novel way to use an existing intervention, and is it capable of diffusing into the US health care system within 3 years? If so, select. (Note: Exclude animal and in vitro studies.)
5. Does this appear to be a different or off-label use of an available drug, biologic, or device? If so, select.
6. Is this a different delivery mode for an existing drug or device? If so, select.
7. Is this being called an innovation AND is it in late-phase development? If so, select.

Questions Considered About Surgical Procedures

Is this a different or novel surgical approach or procedure with potential to disrupt the current standard of care? Consider the following when deciding whether to select:

1. Is this a late-phase human clinical trial? If so, select. (Note: Exclude animal and in vitro studies.)
2. Have signals of interest by US surgeons or institutions been identified through vehicles such as meeting abstracts, editorials, commentaries, case reports, or news releases? If so, select.
3. Is this a new and different clinical indication for an existing surgical procedure? If so, select.
4. Is this a surgical procedure that requires use of procedure-specific tools or devices in development? Consider the following when answering this question:
5. Are the tools subject to approval under FDA’s premarket notification 510(k) or Premarket Approval (PMA) application processes or combination-product process? If a PMA or a 510(k) is applicable, select only if it enables some sort of relevant innovation in surgery AND it is in late-phase clinical trials.

Questions Considered About Nonpharmaceutical Mental and Behavioral Health Interventions

Is this a behavioral intervention purported to be a markedly different or novel approach with potential to disrupt the current care paradigm? Consider the following when deciding whether to select:

1. Is it in a late-phase trial? If so, select.
2. Has there been increased application of an existing but not previously diffused mental health intervention? Does it appear poised to become much more widely diffused? If so, select.
3. Is this a program launch of a different or novel program than currently exists? If so, select.

Questions Considered About Potentially Disruptive Trends

Does this intervention or developing field suggest the possibility for considerable change to the current health care paradigm? Consider the following when deciding whether to select:

1. Is there potential to shift, change, or disrupt patient-oriented outcomes?
2. Is there more than a single instance of the intervention or development?
3. Is it based on sound scientific or technical reasoning? If not, are there signs that it might be adopted anyway?

After subjecting a lead to the appropriate questions, if it appears to meet criteria the scanner downloads the lead, posts it to the leads database, classifies it by clinical area(s) and clinical condition(s) (Table A.4), and, if applicable, links the lead to existing topics and/or trends in the appropriate database. To cast as wide a net as possible, scanners err on the side of inclusion and select ambiguous leads as well as those that clearly meet inclusion criteria. A research assistant then assigns the lead to a horizon scanning analyst for review.

Step 2. Leads Review and Topic Identification

Leads Review

An analyst reviews each lead and uses the following procedure to determine the lead’s initial status (status of lead at time of entry by scanner is New by default) and to prepare for identifying possible topics and/or disruptive trends.

1. The analyst reviews lead content, including the lead document and any metadata collected by the scanner.
2. The analyst tags the lead with one or more identifiers (eg, lead source, product name, manufacturer name, program name, product/intervention name, clinical condition, mechanism of action) related to the intervention or trend addressed in the lead, to enable grouping and sorting of related leads and to quickly identify potential topics or trends mentioned in the lead.
3. The analyst attaches notes about the lead to the lead record (eg, rationale for topic or trend proposal, notes on expected or potential impacts to the health care system, reasons for possible inclusion or exclusion, technology mechanism of action, competing technologies).
4. The analyst determines whether the lead relates to existing topics or trends already entered into topics or trends databases. If so, the analyst links the new lead to the existing topics or trends to facilitate efficient future leads review and topic identification.
5. The analyst selects a status for the lead as follows:
   a. New—This is the default status of lead at the time of entry by the scanner and indicates the lead was recently uploaded by the scanner and has not yet been
reviewed by an analyst. (Note: An analyst may not select this status but it is included here for completeness.)

b. Reviewed—The analyst has reviewed the lead but has not yet taken formal action. This status is meant as a temporary holding place only, and the analyst is expected to include notes to consider during prompt follow-up.

c. Linked—The analyst has reviewed the lead and determined that it contains information pertinent to one or more topics already in the topics database. The analyst links the lead to all associated topics in the topics database by selecting the relevant topic IDs from a dropdown list in the lead record. (In the case that the analyst identifies a new topic that is not in the topics database, the analyst will promptly follow the procedures noted below under Topic Identification. Once the topic has been identified and entered into the topics database, the analyst will promptly return to this step and link the lead to the newly created topic.)

d. Linked trend—The analyst has reviewed the lead and determined it contains information pertinent to one or more disruptive trends in the disruptive trends list. The analyst links the lead to the disruptive trend record by selecting the appropriate trend ID from a dropdown list in the lead record. (In the case that the analyst identifies a new trend that is not in the trends database, the analyst will promptly follow the procedures noted below under Trend Identification. Once the trend has been identified and entered into the trends database, the analyst will promptly return to this step and link the lead to the newly created trend.)

e. Discarded—The analyst has determined that the lead is irrelevant to the Horizon Scanning System for any of several reasons (eg, out of date, pertains to animals, is a duplicate, does not meet criteria upon further evaluation). The analyst provides a brief rationale for discarding the lead. (This status may be selected only during initial leads review. Leads that had been previously considered viable must be archived, as described below.)

f. Archived—The lead had previously been linked to a topic or trend but is no longer relevant for any of several reasons (eg, out of date, superseded by another lead, previously linked topic or trend was excluded from the Horizon Scanning System). The analyst provides a brief rationale for archiving the lead.

**Topic Identification**

If an analyst identifies a potential topic during the leads review process, the analyst subjects the topic to the following questions:

1. Is the intervention in late-phase development for the US health care system? Or, could the intervention be adopted or diffused in the United States without going through a regulatory process (eg, off-label uses, new surgery approaches, care delivery innovations, mental health nondrug interventions)? If yes, consider question 2.

2. Would adoption or implementation of this intervention potentially disrupt any of the following? If yes, for each element selected below and overall, consider the intervention’s potential for disruption (including magnitude and direction of disruption), then consider question 3.
a. Current treatment models
b. Disparities in health care among different patient populations
c. Paradigm shifts (eg, in patient management, understanding disease or condition)
d. Care setting
e. Infrastructure needs of the health care system or health facilities
f. Patient health outcomes and individual burden of disease
g. Population health outcomes and societal burden of disease
h. Clinician learning curve to use the intervention
i. Patient or nonclinician caregiver learning curve to use the intervention
j. Costs of care for the disease or condition

3. Is this intervention’s overall disruptive potential likely to be substantial? Explain. If yes, topic meets criteria for nomination.

If the analyst can confidently answer yes to these 3 questions, she or he enters the topic into the topics database (see below) and schedules the topic for presentation at a topic nomination meeting (see Step 4. Topic and Trend Nomination). If the analyst is certain that at least 1 of these 3 questions cannot be answered affirmatively, the analyst rejects the topic by marking the lead or leads accordingly in the leads database and adding an explanatory note. If the analyst thinks the topic might meet criteria but wishes to obtain external opinion from a relevant expert before proceeding, the analyst schedules the topic for vetting (see Step 3. Topic Vetting).

**Entry of Potential Topics Into Topics Database**

The analyst creates and populates—focusing on PICO (patient population, intervention, comparators, and outcomes)—a new entry in the topics database as follows:

1. Priority area (select one)
   a. Alzheimer’s disease and other dementias
   b. Cancer
   c. Cardiovascular diseases
   d. Mental health
   e. Rare diseases
2. Custom data tags (eg, alternate product names, related terms)
3. Patient population, including important disease stage or condition characteristics
4. Disease or condition name
5. Intervention description, including:
   a. Intervention name
   b. Rationale supporting the intervention’s importance
   c. Brief disease background information
   d. Description (eg, therapeutic class, mechanism of action, method/route of administration, dosing)
6. Intervention class (select one)
   a. Assistive technology
   b. Behavioral health intervention
   c. Biotechnology
   d. Cell therapy
   e. Device
   f. Diagnostic
g. Gene therapy
h. Immunotherapy
i. Implant
j. Information technology
k. mHealth (ie, mobile health)
l. Monoclonal antibody
m. Nanotechnology
n. Pharmaceutical
o. Procedure (nonsurgical)
p. RNA interference therapy
q. Surgery
r. Telehealth
s. Viral vector therapy

7. Developers (eg, sponsors, developers, manufacturers)

8. Development phase (select one)
   a. Phase I
   b. Phase I/II
   c. Phase II
   d. Phase II/III
   e. Phase III
   f. Phase IV
   g. Unphased
   h. Other

9. Key development and regulatory dates
   a. Trial primary completion date (if applicable)
   b. FDA submission planned date (if applicable)
   c. FDA submission date (if applicable)
   d. FDA decision date (eg, Prescription Drug User Fee Act [PDUFA] date) (if applicable)
   e. FDA approval date (if applicable)

10. Regulatory summary, including:
    a. Latest regulatory status and date with links to relevant supporting document
    b. List of special FDA designations with links
    c. Selected pertinent clinical trials with links
    d. Additional notes of interest

11. List of potential comparators to existing options for the same patient population

12. List of potential patient-oriented outcomes the intervention could address

13. Inclusion rationale explaining the analyst’s reason for nominating the topic

After saving the topic record to the topics database, the analyst links all corresponding leads from the leads database. When the analyst is satisfied that the topic record is complete, the analyst may choose to send the topic through expert vetting (see Step 3. Topic Vetting). If the analyst is reasonably confident about the topic’s potential for disruption, the analyst schedules the topic for nomination (see Step 4. Topic and Trend Nomination).
Disruptive Trend Identification
If an analyst identifies a potential disruptive trend during the leads review process, the analyst subjects the trend to the following questions:

1. Does the trend have potential to disrupt, positively or negatively, patient-oriented outcomes, access to care, health disparities, care delivery, staffing, costs, etc.?
2. Is this intervention’s overall disruptive potential likely to be substantial?
3. Is the disruption expected to occur within the next 3 years?

If the analyst answers yes to these 3 questions, the analyst enters the trend into the trends database (see below) and schedules the trend for presentation at a trend nomination meeting (see Step 4. Topic and Trend Nomination). If the analyst answers no to at least one of these 3, he or she rejects the trend by marking the lead or leads accordingly in the leads database and adding an explanatory note.

Entering a Potential Disruptive Trend Into the Trends Database
The analyst creates and populates a new entry in the disruptive trends database as follows:

1. Trend title
2. Description
3. Clinical areas likely to be affected
4. List of potential threats (ie, cons) posed by the trend
5. List of potential opportunities (ie, pros) posed by the trend

After saving the trend record to the trends database, the analyst links all corresponding leads from the leads database. When the analyst is satisfied that the trend record is complete, the analyst schedules the trend for nomination (see Step 4. Topic and Trend Nomination).

Step 3. Topic Vetting
If the analyst is uncertain of the extent or magnitude of a topic’s potential for disruption, the analyst may seek expert opinion through the topic vetting process before proceeding to a topic nomination meeting (see Step 4. Topic and Trend Nomination). A brief summary of the topic’s PICO information is sent to a clinical expert in the field to gauge early impressions about the intervention’s potential for disrupting the current standard of care. The expert is asked to review the topic summary then complete a brief questionnaire, structured as follows:

1. Do you think the intervention has potential to cause substantial disruption (positive or negative) to health care in the United States? Yes or No. If yes, proceed to question 2.
2. In which of the following areas will the intervention cause disruption (positive or negative)? (Select as many as apply.)
   a. Patient outcomes
   b. Access to care
   c. Health disparities
   d. Care delivery
   e. Staffing
   f. Costs
   g. Other (please specify)
3. Provide a brief rationale for your selection(s) above. (1000 characters or fewer)

The completed questionnaire is returned to the analyst, who adds the results to the topic record and uses the input to inform the decision whether to nominate a topic for entry into the Horizon Scanning System or to exclude it. The analyst adds a brief note to the topic record explaining her or his decision. If the analyst decides to nominate the topic, she or he schedules it for presentation at a topic nomination meeting (see Step 4. Topic and Trend Nomination).

Step 4. Topic and Trend Nomination

Topics and trends scheduled for nomination during the topic and trend identification process are presented at nomination meetings, which occur monthly or more often, if needed, depending on the number of potential topics analysts have identified for consideration by the team.

Nomination Meetings

Attendees include both voting and nonvoting members. Voting members are horizon scanning analysts, project manager, senior technical advisor, information team leader, knowledge manager, and patient engagement specialist. Nonvoting members include medical librarians, research assistants, stakeholder engagement coordinator, and sometimes other invited staff, outside experts, and patient or caregiver representatives.

During a nomination meeting, each analyst presents several potential topics or trends for group consideration. Analysts present topics by describing the PICOs, development status, relevant data, and a brief rationale for inclusion (ie, why the analyst expects this topic to be disruptive). Analysts present trends by describing what the trend is, the potential threats and opportunities it poses, and a brief rationale for inclusion (ie, why the analyst expects the trend to be disruptive). Each topic or trend presentation takes about 3 to 5 minutes.

After each presentation, attendees consider whether the trend or topic meets criteria and whether it has potential to be significantly disruptive to health care in the United States. A brief discussion may take place, after which a vote is taken regarding whether to include the topic or trend in the HCHSS. Voting is completed in a blinded manner. A topic or trend must receive a majority vote to be included. If a tie vote occurs, the HCHSS project manager (or another senior team member appointed by the project manager) breaks the tie.

Included topics are those the team agrees have potential to cause disruption (within the context of their specific use) and have entered late-phase trials or have some FDA designations that signal potential for entering clinical care within 2 to 3 years. Included trends are those the team agrees are relevant to PCORI’s interests and have potential to cause significant disruption to health care in the United States within the next 3 years.
Post-Meeting Procedure

Every 3 months, short profiles of all included topics and trends are generated and reported in the quarterly Status Report (see Step 5. Status Report).

For included topics with late-phase data or for which a developer has issued sufficient data to make a regulatory submission to FDA, searchers conduct detailed searches to gather information analysts use to develop in-depth profiles (see Step 6. Topic and Trend Profile Development). These profiles are then sent for review and commentary from relevant clinicians, health systems experts, and patients or patient representatives to determine perceptions about the potential for disruption (see Step 7. Stakeholder Engagement and Survey Process).

For included trends, analysts may also request detailed searches. The trend records are then revised and edited (see Step 6. Topic and Trend Profile Development) before being sent to internal ECRI stakeholders for comment (see Step 7. Stakeholder Engagement and Survey Process).

Step 5. Status Report

Four times each year (once per quarter), the team prepares a Status Report that provides an inventory of all topics and trends included in the HCHSS at that time. The reports also list topics and trends that were previously included but have been archived from the system during the quarter. The Status Report is organized into 6 sections. The first 5 sections include topics contained in each of the 5 PCORI-defined priority areas (1 section for each priority area). The sixth and final section lists disruptive trends. Each section consists of 1 to 3 tables for (1) new topics or trends added since the previous Status Report, (2) currently monitored topics or trends, and (3) topics or trends archived during the current quarter.

Topic descriptions include the PICO and other key information (eg, developers and regulatory status). Trend descriptions include the trend title, description, and lists of potential threats and opportunities. In the archived tables, we include the reason each topic or trend was archived (see Step 9. Topic Monitoring and Updating: Archiving Topics).

Step 6. Topic and Trend Profile Development

Topics and trends voted in during the nomination process are developed further into profiles before being sent to stakeholders for comment and subsequently considered for inclusion the High Potential Disruption Report (see Step 8. High Potential Disruption Report). However, the processes differ between these content types. We describe those processes in this section.

Topic Profile Development

Queuing and Assigning Topics for Profile Development

Topics with available late-phase data (or earlier-phase data with special designations that could make an intervention eligible for regulatory submission to FDA) are queued for topic profile
development. Topics are queued when these criteria are met, which may be immediately after topic nomination or at any subsequent point. Each queued topic is assigned to an analyst covering that clinical area for topic profile development.

Searching for Topic-specific Information
Each topic is also assigned to a medical librarian, who creates a detailed search strategy and searches appropriate databases to obtain topic-specific information (eg, published and ongoing trial information, manufacturer information, news). Medical librarians create parallel search strategies for each resource searched. The search strategy and search results are recorded on a standardized data entry form maintained in the system. Medical librarians also set up topic-specific alerts for ongoing topic monitoring (see Step 9. Topic Monitoring and Updating).

ECRI’s database management team standardizes search results from public and proprietary bibliographic databases for entry into the citation (reference) management system and creates records in the citation management system for information retrieved from nondatabase sources (such as manufacturer websites). These results are delivered electronically to the assigned analyst.

Developing Topic Profiles
The assigned horizon scanning analyst reviews and organizes all search result materials, selects relevant materials, requests follow-up searches as needed, and drafts a topic profile, structured as follows:

1. Topic title
2. Intended patient population
3. Intervention description
4. Potential comparators
5. Patient-oriented outcome measures
6. Manufacturers or developers
7. Development and regulatory status
8. Cost information
9. Evidence development status
10. References

Managing Document Requests and Reference Lists
Throughout the topic-profile development process, database team members process and manage analysts’ document requests. They work closely with the medical librarians to obtain full-text documents and distribute them electronically to the requesting analyst. They also record analysts’ requests, document the delivery in the citation management system, and generate reference lists according to the documents analysts select for inclusion in the profiles they write.

In addition, a citations specialist enters each set of stakeholder comments (see Step 7. Stakeholder Engagement and Survey Process) received on a topic into the document management system and assigns it a citation number so analysts can reference stakeholder perspectives (by stakeholder category) when they synthesize results of the comment process that led to designating topics as having high potential for disruption (see Step 8. High Potential Disruption Report).
Trend Profile Development
Trends are immediately queued for profile development after the trend nomination meeting. The trend profile development is automatically assigned to the analyst who nominated it. The analyst returns to the trend record in the trends database, revises the description and other fields as needed, based on discussion from the nomination meeting, then submits it for editorial review. The project manager reviews the trend profile. It is then copyedited and posted to an internal ECRI online bulletin for stakeholder comment (see Step 7. Stakeholder Engagement and Survey Process).

Step 7. Stakeholder Engagement and Survey Process
Twice annually—in May and November—the horizon scanning team prepares a report on topics and trends deemed to have high potential for disruption (see Step 8. High Potential Disruption Report). To support this effort, all included topics and trends that have been developed as profiles (see Step 6. Topic and Trend Profile Development) are sent to various, carefully selected stakeholders for comment and ratings. ECRI employs a robust process to recruit and engage stakeholders (eg, medical experts, patients, caregivers) in the horizon scanning process. Below, we describe our recruitment, engagement, and stakeholder comment processes.

Stakeholder Recruitment and Engagement

Medical and Scientific Experts
ECRI maintains and continues to build an active network of more than 300 medical and scientific experts throughout the United States and abroad. ECRI’s expert network spans more than 25 specialties and includes clinicians and researchers with an average of more than 8 years’ experience in their fields.

ECRI uses a standard procedure for identifying, recruiting, and contracting these experts (eg, physicians, nurses, physician assistants, allied health professionals, researchers, health systems professionals) for its horizon scanning efforts:

1. A horizon scanning stakeholder engagement coordinator identifies specific clinical areas of need to determine the appropriate type and level of expertise needed for the task.
2. The coordinator works with a horizon scanning analyst and medical librarian to search bibliographic databases, including SCOPUS and PubMed, to find authors of recent, high-quality peer reviewed medical literature pertinent to the topic. The coordinator may also contact existing members of ECRI’s stakeholder network to obtain recommendations.
3. The coordinator contacts the expert via email and/or telephone to discuss the nature of the project, expectations, conflicts of interest, honorariums payment, etc.
4. When the coordinator is satisfied the expert is qualified for the task and the expert has agreed to participate, the coordinator enters the expert’s contact information in the horizon scanning stakeholder database and requests that the individual complete an
Internal Revenue Service (IRS) form W-9 (US) or W-8 (non-US) to enable payment of honorariums.

5. The coordinator may then contact the expert as needs arise (see Comment Process for Topics below).

Patients, Patient Representatives, and Caregivers

A hallmark of the PCORI HCHSS is the inclusion of patient, patient representative, and caregiver perspectives in addition to clinical, health systems, and research perspectives. Including these additional perspectives introduces more diversity of thinking about an intervention’s potential to disrupt health care.

ECRI also uses a standard procedure for identifying, recruiting, and engaging patients, patient representatives, and caregivers for its horizon scanning efforts. Stakeholders are recruited from credible community sources, such as national advocacy organizations or health care consortiums (eg, Consumers United for Evidence-based Healthcare). We summarize the recruitment and engagement process as follows:

1. A horizon scanning patient engagement specialist (PES) searches the internet for organizations relevant to the 5 priority areas (eg, cancer) or clinical condition (eg, ovarian cancer), identifies a point of contact (eg, outreach coordinator), and logs information about the identified organizations, such as the mission and contact details, in a Microsoft Excel spreadsheet.

2. The specialist emails the point of contact, briefly describing the HCHSS and the importance of patient and caregiver stakeholders as commenters, and asks for support in identifying potential participants. The PES also extends an invitation to further discuss the project during a conference call.

3. Once identified, a horizon scanning stakeholder coordinator emails the patient, patient representative, or caregiver a welcome message describing the HCHSS and commenter responsibilities and requests details about the stakeholder’s experience (eg, cystic fibrosis) and role (eg, caregiver).

4. If the stakeholder is interested in participating, the coordinator enters the stakeholder’s contact information in the horizon scanning stakeholder database and requests that the individual complete an IRS form W-9 (US) or W-8 (non-US) to enable payment of honorariums. (Stakeholder contact and personal information is maintained securely in a HIPAA-compliant database and is never divulged to any third parties.)

5. The stakeholder receives an email with a 10-minute audiovisual presentation describing project goals, the importance of engaging patients and caregivers in the process, key terminology, and how comments are used. A sample report and comment form are also provided.

6. The coordinator may then contact the stakeholder as needs arise (see Comment Process for Topics below).

7. After a stakeholder completes a topic survey for the first time, the stakeholder receives a thank-you email with a link to a brief satisfaction survey requesting feedback about the participation experience, suggestions for improvement, and recommendations of topics that might meet criteria for inclusion in the HCHSS.
ECRI Internal Stakeholders
In addition to recruiting external medical experts, patients, and caregivers, ECRI takes advantage of its own rich repository of expertise inherent in its employees. ECRI horizon scanning engages more than 80 ECRI internal stakeholders, representing the following perspectives: health care business and finance, clinical engineering, health systems, health care generalist, information technology, nursing, physician, physician assistant, and research.

Survey Process for Topics
Stakeholder Selection for Topic Reviews
For each topic profile, we invite 5 to 9 relevant stakeholders—including those with clinical, health systems, research, patient or patient representative, and caregiver perspectives—to provide input on the topic.

Stakeholders are carefully selected based on their expertise or experience with the specific topic and subject matter. Medical expert stakeholders are expected to have domain expertise in one or more of the following areas: clinical or research areas, health systems administration, health disparities, health technology assessment, health services assessment, comparative effectiveness research, and health care business issues. Patients or patient representatives and caregivers are expected to have direct experience with the topic’s disease or condition.

Stakeholders for each topic are generally US-based medical experts, patients, and caregivers because they are most familiar with the US health care system and better able to respond to the disruption parameters we ask them to consider and rate. However, we may occasionally invite non-US stakeholders to comment if a particular topic warrants.

For each topic, a horizon scanning stakeholder engagement coordinator contacts an appropriate group of stakeholders to determine their availability and interest in reviewing a topic. If a stakeholder accepts the assignment to provide comments on the topic, the coordinator sends the topic profile along with a link to a brief online survey.

Stakeholder Surveys for Topics
Stakeholders read the profile, then complete a brief online survey to rate potential for disruption to the current standard of care and provide a rationale for their ratings. We use 2 separate surveys—one for medical experts (Appendix B) and one for patients, patient representatives, or caregivers (Appendix C)—to elicit stakeholder comments and ratings. The survey asks the stakeholder to provide ratings (on a scale of 1 [no disruption] to 4 [large disruption]) and rationales to elicit their perspectives on the topic’s potential to disrupt health care.

When a stakeholder submits a completed survey, the results are logged into a database containing all stakeholder comments and ratings.

Although we seek a maximum of 9 stakeholders to provide comment for each topic profile, topics become eligible for consideration in the High Potential Disruption Report after we receive at least 5 sets of comments on a topic, including at least 2 external (to ECRI) stakeholders. Each set of comments and ratings remains in the database for subsequent analysis and synthesis for the next
High Potential Disruption Report. In that report, we identify stakeholders by their respective roles (eg, clinical, research, health systems, patient representative), but not by name.

Stakeholders provide opinions independently based on their respective knowledge about the technology or services, standard of care, patient experience, and/or health care system. No individual’s comments are intended to represent an entire group or field.

Topic profiles with complete sets of stakeholder comments may be updated over time and reissued to obtain updated stakeholder comments as important new information becomes available that might change or inform a stakeholder’s perspective (see Step 9. Topic Monitoring and Updating).

**Balancing Potential Conflicts of Interest**

Knowledgeable health care professionals, patients, or caregivers asked to comment could have a personal, intellectual, or financial conflict of interest related to a topic. In fact, those with vested interests in new technologies, services, and innovations may provide critical insights about those topics. We ask stakeholders to declare potential conflicts of interest on the survey form. Those with potential conflicts of interest are not categorically disqualified from participating. Instead, we seek to balance their views with inputs from other neutral parties, including ECRI’s own experts. We limit the number of participants with potential conflicts of interest to 2 per topic.

**Survey Process for Trends**

**Stakeholder Selection for Trends Reviews**

We invite a pool of about 30 ECRI internal stakeholders—representing health care business and finance, clinical engineering, health systems, health care generalist, information technology, nursing, physician, physician assistant, and research perspectives—to provide input on each trend.

All stakeholders participating in the trend-review process are prescreened by the horizon scanning project manager and knowledge manager. They are also provided with educational materials about how to think about trends and the task at hand and ongoing support throughout the process.

All trends included during the nomination process are listed on an internal ECRI online bulletin board. Each trend listed includes the trend title and a trend summary. Any stakeholder from the stakeholder pool may self-select to review a trend, based on the stakeholder’s expertise and interest. The horizon scanning project manager monitors the process to ensure that at least 5 stakeholders representing appropriate perspectives review each trend.

**Stakeholder Surveys for Trends**

If a stakeholder chooses to review a trend, the stakeholder reads the trend summary and then completes a brief online survey to elicit the stakeholder’s perspectives on the trend’s potential to disrupt health care (Appendix D).

When a stakeholder submits a completed survey, the results are logged into a database containing all stakeholder comments and ratings. Each set of comments and ratings remains in the
database for subsequent analysis and synthesis for the next High Potential Disruption Report. In
the report, we identify stakeholders by their respective roles (ie, business and finance, clinical
engineering, health systems, health care generalist, information technology, nursing, physician,
physician assistant, and research), but not by name.

Stakeholders provide opinions independently based on their respective knowledge, and no
individual’s comments are intended to represent an entire group or field.

Step 8. High Potential Disruption Report
The stakeholder survey process (Step 7. Stakeholder Engagement and Survey Process) helps
determine which topics and trends have the highest potential to significantly disrupt patient care in
some manner, such as patient outcomes, access to care, health disparities, care delivery, staffing,
and costs. Twice annually, the horizon scanning team reviews all stakeholder comments and
ratings (for currently included topics and trends) received in the past 12 months. This review
begins a process culminating in the production and delivery of the High Potential Disruption
Report.

The selection process differs between topics and trends. We discuss those processes,
respectively, below.

Topic Selection Process
Stakeholder Ratings Review and Analysis
To be considered for inclusion in the High Potential Disruption Report, a topic must be active (ie,
not archived) and must have received a minimum of 5 stakeholder surveys (including at least 2
surveys completed by expert stakeholders external to ECRI) within the past 12 months.

To ensure the High Potential Disruption Report contains only those topics that stakeholders
agreed have high potential to be significantly disruptive to health care in the United States, a topic
must also meet a minimum disruption rating threshold (ie, low-moderate disruptive potential) to be
considered for inclusion.

To determine which topics meet this disruption-rating threshold, we calculate an overall
disruption score (ODS) for each topic, as follows:

1. Calculate the mean average for each survey rating (see Appendices B and C).
2. Calculate the mean of all means calculated in step 1.
3. Compare the result from step 2 with the mean average of the ratings received for
question 6 (ie, overall disruption potential).
4. Select the highest of the 2 values generated from steps 2 and 3. This is the ODS.

This process generates an ODS for each topic between 1 and 4 (1 = no disruptive potential;
4 = high disruptive potential). The ODS is used to determine whether the topic will be
automatically included, automatically excluded, or scheduled for discussion for possible inclusion
at the final topic selection meeting.
**Topics Included or Excluded Based on ODS**

Generally, topics with an ODS of 3.2 or higher (high-moderate to high overall disruptive potential) are included in the High Potential Disruption Report, and topics with an ODS of 2.8 or lower (ie, low-moderate to no disruptive potential) are excluded. However, analysis of stakeholder comments must generally support conclusions suggested by ratings. For topics having ratings with high variance (ie, stakeholder ratings show wide variation), the analyst assigned to the applicable clinical priority area carefully reviews the topic profile, ratings, and comments to determine whether the topic should be included (for topics with ODS of 3.2 or higher), excluded (for topics with ODS of 2.8 or lower), or scheduled for discussion for possible inclusion at the High Potential Disruption Report topic selection meeting. Topics selected for inclusion during this process are assigned to analysts for report drafting (see Report Drafting, Production, and Structure).

**Topics Scheduled for Discussion for Possible Inclusion**

Topics with an ODS between 2.8 (ie, low-moderate disruptive potential) and 3.2 (ie, high-moderate disruptive potential) are scheduled for discussion at the High Potential Disruption Report topic selection meeting (see Topic Selection Meeting below). In addition, as discussed above, some topics with an ODS of 3.2 or higher or 2.8 or lower may be scheduled for discussion at the meeting if the ratings received for the topic show high variance.

Each scheduled topic is reviewed by the analyst assigned to the applicable clinical priority area. The analyst rereads the topic profile and reviews each survey received for the topic, paying particular attention to stakeholder comments. The analyst then prepares a brief summary of stakeholder comments, selects a recommendation for the topic (include, exclude, or uncertain), and writes a brief rationale supporting the recommendation. The analyst will present this information at the topic selection meeting.

**Topic Selection Meeting**

The HCHSS team meets to discuss topics that have not been automatically included or excluded during the ratings and comments review processes (above).

The assigned analyst for each topic presents a summary of stakeholder comments and ratings received for the topic (about 3 minutes per topic). A brief discussion (about 3 minutes per topic) then takes place, during which team members may ask questions or provide perspectives regarding the topic’s disruptive potential. Following the discussion, a blinded vote is taken to determine whether the topic should be included in the High Potential Disruption Report. The topic must receive a majority affirmative vote to be included. Topics selected for inclusion are assigned to analysts for report drafting (see Report Drafting, Production, and Structure).

**Trends Selection Process**

To be considered for inclusion in the High Potential Disruption report, a trend must be active (ie, not archived) and must have received a minimum of 5 stakeholder surveys within the past 12 months. The trend must also meet the selection criteria described below to be included.
Trends are selected for inclusion in the High Potential Disruption Report based on stakeholder perspectives regarding the trend’s overall disruptive potential, timing, and likelihood. To be included, stakeholders must indicate that a trend has a high-moderate to high overall disruptive potential and is somewhat to highly likely to cause disruption within the next 3 years in the United States.

Generally, a trend that receives mean average ratings (see Appendix D) as follows for each of the 3 points below will be selected for inclusion:

1. Overall disruption potential—3.2 or higher (i.e., high-moderate to high disruptive potential)
2. Timing of disruption—2 or higher (i.e., occurring within about 3 years)
3. Likelihood of disruption—2.8 or higher (i.e., somewhat likely to highly likely)

Analysis of stakeholder comments must generally support conclusions suggested by ratings. For trends with borderline ratings, high variance, or questionable comments, we use a brief review process to determine inclusion or exclusion. A 3-member panel (project manager, knowledge manager, lead analyst) reviews ratings and comments. This panel then takes a vote. A majority affirmative vote selects the trend for inclusion.

The selected trends are assigned to analysts for report drafting (see Report Drafting, Production, and Structure).

Report Drafting, Production, and Structure

After topic and trend selection, the project manager creates a production schedule and assigns the selected topics and trends to the appropriate analysts for report drafting.

Analysts write individual summaries (fewer than 2000 words) for each topic or trend. Topic summaries include highlights, PICO information, an evidence development summary, manufacturer and regulatory information, cost information (if available), and a summary of key stakeholder perspectives. Trend summaries include highlights, a trend description, a list of clinical areas potentially disrupted, lists of potential opportunities (i.e., pros) and threats (i.e., cons), and a summary of key stakeholder perspectives.

The individual summaries are compiled into chapters: one chapter for each of the 5 PCORI-defined priority areas and one chapter for potentially disruptive trends. After a chapter has been compiled, the project manager reviews all content and writes a chapter summary, which provides basic information and statistics about topics or trends included in the chapter and currently monitored or recently archived in the HCHSS.

The senior technical reviewer, medical copyeditor, and project director then carefully review each chapter before compilation into the final report. After compilation, the project manager reviews the content and writes the overall reporting period summary, which provides basic information and statistics about topics or trends included in the report and currently monitored or recently archived in the HCHSS.
After the medical copyeditor performs a final proof of the document, the project manager delivers the report to PCORI. ECRI addresses PCORI’s edits, comments, and questions as required before PCORI publishes the report on its website.

**Step 9. Topic Monitoring and Updating Process**

The HCHSS team monitors all topics included in the PCORI HCHSS—regardless of whether a topic has been developed as a topic profile—for new information. Scanners use keywords and controlled vocabulary terms to monitor and search resources. When possible, scanners create automated alerts to capture new topic-specific information on an ongoing basis. These monitoring activities can trigger a change in topic status depending on what has occurred with its development or diffusion status.

**Updating Topics**

New information on topics already in the system is entered into the leads database as a lead record, which is linked to the relevant topic record in the topics database and assigned to the appropriate analyst for review. The analyst reviews the new information and, if warranted, may recommend action on the topic. For example, if late-phase data have recently become available for a topic that previously had no late-phase data, the analyst recommends adding the topic to the topic profile queue to develop a topic profile. If the analyst discovers the intervention’s manufacturer has ceased development, the analyst recommends archiving the topic in the topics database and/or removing it from the topic profile queue (see Archiving Topics). The project manager (or another senior member of the team appointed by the project manager) approves and makes the necessary changes in the system.

Additionally, new information gathered may trigger a content update to an included topic record in the topics database or to a topic profile. Examples of triggers for topic updates include the following:

- Changes regarding US regulatory submissions (eg, Biologic License Application, New Drug Application, Premarket Approval Application), including new submissions, advisory panel recommendations, and FDA decision dates
- Start of new trials or announcement/publication of late-phase data on the topic
- Major changes in adoption and/or implementation issues, including availability of new comparators
- Company mergers that affect product development (product development may be delayed or halted altogether)
- Company selling of research and development rights for a product
- Rapid increase in the volume and sources of published literature on a procedure or care innovation (eg, uptick in reports on a surgical approach, such as single-incision laparoscopic surgery; uptick in gray literature on evidence-based hospital design)
- Changes to the intervention name (eg, a tradename becomes available)
Topic profiles are placed back in the topic profile queue for updating and rescheduled for stakeholder comments when new information becomes available that the HCHSS team concludes could change perspectives. Some examples include:

- New data shed new light on an intervention, such as the following:
  - Additional, stronger, confirmatory data that could change perspectives on potential disruption
  - Safety data that could change perspectives
  - New data that are inconsistent with prior data provided to experts
  - A newly issued patient safety alert could signal a safety- or efficacy-related change in perspectives
- FDA issued a decision that could affect experts’ perspectives, such as a Complete Response Letter from FDA to a developer or manufacturer, which then decides to continue development and initiate new trials that could change expert perspectives, or an advisory panel’s negative recommendation.
- Postmarket events (within 1 year of FDA approval) occurred that could change the premarket projections of impact, such as a much slower uptake than anticipated, apparent lack of acceptance by clinicians or patients, no reimbursement, access issues, position statements by professional societies, or market withdrawal of competing interventions.

If no new information has been found through scanning activities during the previous 12 months on a topic with a topic profile, we conduct new searches to determine whether the topic remains viable and/or new stakeholder comments are warranted.

Archiving Topics

We continuously monitor topics to determine whether they remain viable or should be archived. A topic may be archived at any time if new information becomes available indicating that the topic no longer meets criteria for inclusion in the PCORI HCHSS. All topics archived during each quarterly reporting period are indicated in that period’s Status Report, along with a brief rationale regarding the reason for archiving the topic. Some reasons for archiving a topic include the following:

- The intervention fails to meet endpoints in trials and product development ceases.
- Companies’ financial resources to continue development have been exhausted.
- The intervention diffusion is 1 year past regulatory approval or, if not subject to FDA regulation, has diffused beyond early adopters.
- The topic is no longer novel or innovative because other topics in its class have reached diffusion in the health care system, rendering the topic identical to or very similar to an existing intervention and therefore no longer addresses a significant unmet need.
- The topic has completed stakeholder comment and ratings, and stakeholders have concluded the topic has no potential for high disruption in any of the parameters of interest to PCORI or the entities its research supports.
## Appendix A. Scanning and Searching Resources

### Table A.1. Medical Websites, Newsletters, Trade Publications, and Peer Reviewed Publications Reviewed by ECRI Medical Librarians and/or Horizon Scanning Analysts

<table>
<thead>
<tr>
<th>Resource Name and Type (1–12; See Key at End of Table)</th>
<th>Description</th>
<th>Biologics Biotech</th>
<th>Device</th>
<th>Drug</th>
<th>In Vitro Diagnostics</th>
<th>Procedure/Therapy</th>
<th>Process</th>
<th>Off-label Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>360Dx 2, 3, 4, 8</td>
<td>News resource for emerging economic and technological trends in the clinical diagnostic market</td>
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<tr>
<td>ACM TechNews 2, 3, 4, 8</td>
<td>Digital newsletter published 3 times weekly that summarizes news on established and emerging areas of computer science; trends in information technology; and related science, society, and technology news. Links directly to source article.</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
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<td>X</td>
</tr>
<tr>
<td>AdvaMed 2, 3, 4, 5, 8</td>
<td>Advocacy group for medical device industry; provides news, information on issues and advocacy efforts, case studies on various technologies. AdvaMed SmartBrief is a daily email summarizing top medical technology news.</td>
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<td>X</td>
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<tr>
<td>Advances in Pharmacy ASHP Daily Briefing 2, 3</td>
<td>Daily email briefing summarizing key medical and health care news from the previous 24 hours; targeted to health system pharmacists</td>
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<tr>
<td>AHA Emerging Science Series 1</td>
<td>Online forum for late-breaking clinical trials, key updates of previously presented trials, late-breaking science, new analyses or substudies, major bench-to-bedside breakthroughs, and more</td>
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<td>X</td>
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<tr>
<td>AJMC Rare Disease News 2</td>
<td>Resource center for rare disease news, research, and media content</td>
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<tr>
<td>Alpha Galileo 3</td>
<td>Distributor of news releases and other information from science, health, technology, the arts, humanities, social sciences, and business</td>
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<td>Alzheimer’s &amp; Dementia: The Journal of the Alzheimer’s Association 1, 2, 4</td>
<td>Content emphasizes interdisciplinary investigations and integrative/translational articles related to etiology, risk factors, early detection, disease modifying interventions, prevention of dementia, and applications of new technologies in health services</td>
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<tr>
<td>Resource Name and Type (1–12; See Key at End of Table)</td>
<td>Description</td>
<td>Biologics Biotech</td>
<td>Device</td>
<td>Drug</td>
<td>In Vitro Diagnostics</td>
<td>Procedure/Therapy</td>
<td>Process</td>
<td>Off-label Use</td>
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<tr>
<td>Alzheimer’s Research News—ScienceDaily 1, 2, 4, 5</td>
<td>Latest research on Alzheimer’s disease and Alzheimer’s symptoms, such as memory loss and senile dementia</td>
<td></td>
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<tr>
<td>American Journal of Geriatric Psychiatry 1, 2, 4</td>
<td>Contains peer reviewed articles on the diagnosis and classification of psychiatric disorders of later life, epidemiological and biological correlates of mental health of older adults, and psychopharmacology and other somatic treatments</td>
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<tr>
<td>American Association for Clinical Chemistry 2, 3, 4, 5, 8</td>
<td>Global scientific and medical professional organization dedicated to clinical laboratory science and its application to health care</td>
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<tr>
<td>Annals of Vascular Surgery 1, 2, 4</td>
<td>Published eight times a year; invites original manuscripts reporting clinical and experimental work in vascular surgery for peer review</td>
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<tr>
<td>ASCO: Journal of Clinical Oncology 1, 2, 11</td>
<td>Authoritative resource for disseminating significant clinical oncology research</td>
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<tr>
<td>Aunt Minnie Insider 2, 6, 11</td>
<td>Aggregates information on radiation therapies and technologies</td>
<td>X</td>
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<tr>
<td>BioPharma Dive 2, 3, 5, 6</td>
<td>In-depth journalism and insight into the most impactful news and trends shaping biotech and pharma. The newsletter and website cover topics ranging from clinical readouts to FDA approvals, gene therapy to drug pricing, and mergers and acquisitions to research partnerships.</td>
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<tr>
<td>BioPharma Reporter 2, 3</td>
<td>Provides daily and weekly newsletters to subscribers; seeks out news and data of value to decision makers in the biopharmaceutical development and manufacturing sector</td>
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<tr>
<td>BioPhotonics 2, 3, 5, 7, 8</td>
<td>Monthly digital magazine reporting on developments and techniques in photonics relevant to medicine and biotechnology; features articles and industry, product, and business news</td>
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<td>X</td>
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<tr>
<td>BioSpace 2, 3</td>
<td>Leading online source for breaking industry news and expert analysis. BioSpace has accelerated communication and discovery among business and scientific leaders within the life sciences for more than 30 years.</td>
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<tr>
<td>Resource Name and Type (1–12; See Key at End of Table)</td>
<td>Description</td>
<td>Biologics</td>
<td>Device</td>
<td>Drug</td>
<td>In Vitro Diagnostics</td>
<td>Procedure/Therapy</td>
<td>Process</td>
<td>Off-label Use</td>
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<tr>
<td>Biotech Regulatory News</td>
<td>Breaking regulatory news in biotech</td>
<td>X</td>
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<tr>
<td>BioSpace 2, 3, 10</td>
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<tr>
<td>Biotechnology Industry News</td>
<td>Breaking news on the biotechnology industry</td>
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<td>BioSpace 2, 3, 10</td>
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<tr>
<td>Bioworld MedTech 2, 9, 10</td>
<td>Covers new product developments, company news, regulatory activity, legislative actions, strategic alliances, sales and mergers, and market updates</td>
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<tr>
<td>BizJournals 2, 4, 5, 7</td>
<td>Digital weekly business newspapers from 41 major US cities</td>
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<td>BMJ 1, 2, 4, 5, 6, 7, 9</td>
<td>Digital weekly journal; publishes original medical research to improve patient outcomes and influence the debate on health care; continuously updated website</td>
<td>X</td>
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<tr>
<td>Business Week 2, 3, 5, 6</td>
<td>Weekly magazine that reports on international business, financial, and investment news</td>
<td>X</td>
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<tr>
<td>California HealthCare Foundation 1, 4</td>
<td>Nonprofit grant-making philanthropic organization focused on clinical outcomes and quality of life, reducing barriers to efficient, affordable health care, promoting transparency and accountability, and implementing health reform in California</td>
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<tr>
<td>CancerNetwork 1, 2, 6, 8, 9</td>
<td>Website that aggregates medical information on cancer treatment, including original medical research and news updates</td>
<td>X</td>
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<tr>
<td>Cardiology Today 1, 2, 4, 8, 9</td>
<td>Information source for cardiovascular medicine professionals. Reports on emerging technologies; techniques and medical therapies; and clinical, therapeutic, industry, and socioeconomic issues</td>
<td>X</td>
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<tr>
<td>Cardiovascular Update 1, 2</td>
<td>E-newsletter from the Mayo Clinic; reports on cutting-edge diagnostic and therapeutic techniques offered in its subspecialty clinics</td>
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<tr>
<td>CenterWatch 2, 3, 9, 12</td>
<td>Provides a variety of clinical research products and services, including a weekly rundown of current events and news</td>
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<tr>
<td>Circulation 1, 2, 4, 5, 7, 9</td>
<td>Peer reviewed journal from the American Heart Association that publishes original medical research related to cardiovascular issues</td>
<td>X</td>
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<tr>
<td>Resource Name and Type (1–12; See Key at End of Table)</td>
<td>Description</td>
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<td>Device</td>
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<td>In Vitro Diagnostics</td>
<td>Procedure/Therapy</td>
<td>Process</td>
<td>Off-label Use</td>
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<tr>
<td>Clinical Trials / Drug Trials News 2, 3</td>
<td>Latest clinical trials and drug trials research from prestigious universities and journals throughout the world</td>
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<td>Clinical Trials News (Phase II)</td>
<td>Breaking news on Phase II clinical trials</td>
<td>X</td>
<td>X</td>
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<td>Clinical Trials News (Phase III)</td>
<td>Breaking news on Phase III clinical trials</td>
<td>X</td>
<td>X</td>
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<tr>
<td>ClinicaSpace Focus 2, 3, 6, 8</td>
<td>Online community for the Clinical Research industry; delivers—through user-friendly navigation—daily news, events, company profiles, stocks, blogs, and other relevant information from the sector</td>
<td>X</td>
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<tr>
<td>Commonwealth Fund 1, 4</td>
<td>Private foundation that promotes a high-performing health care system, particularly for society’s most vulnerable, by supporting independent research on health care issues and making grants to improve health care practice and policy</td>
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<tr>
<td>Diagnostic Imaging 2, 6, 8, 11</td>
<td>Digital newsletter and website providing news and information about radiology</td>
<td>X</td>
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<tr>
<td>Drugs.com—Clinical Trials 2, 3</td>
<td>Information about recently completed clinical trials</td>
<td>X</td>
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<tr>
<td>Drugs.com—FDA MedWatch Alerts 2, 3, 8</td>
<td>Comprehensive and up-to-date drug news for both consumers and health care professionals</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Drugs.com—New Drug Applications 2, 3</td>
<td>Information of all new drug applications in the pipeline</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Drugs.com—New Drug Approvals 2, 3, 8, 10</td>
<td>Up-to-date information on the latest FDA drug approvals; includes list of most-recent approvals, the conditions approved for, and the approval history</td>
<td>X</td>
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<tr>
<td>ECRI Institute Product Briefs and Hotline Responses 1, 4, 8</td>
<td>Researched responses to questions from ECRI Institute member hospitals, health plans, and other subscribing organizations about efficacy and effectiveness of health care technologies, services, and factors affecting diffusion and implementation</td>
<td>X</td>
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<tr>
<td>Embase Conference Coverage 1, 11</td>
<td>Newsfeed of abstracts indexed by Embase covering more than 4700 biomedical conferences</td>
<td>X</td>
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<tr>
<td>Endpoints (Endpoint News) 2</td>
<td>Biopharmaceutical news</td>
<td>X</td>
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<tr>
<td>Resource Name and Type (1–12; See Key at End of Table)</td>
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<td>EurekAlert! 3</td>
<td>American Association for the Advancement of Science portal for press releases from universities, medical centers, journals, government agencies, corporations, and other research organizations</td>
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<tr>
<td>European Radiology 1</td>
<td>Peer reviewed journal that publishes original scientific research and reviews in radiology</td>
<td>x</td>
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<tr>
<td>Evidence Street 1</td>
<td>Blue Cross and Blue Shield Association’s Technology Evaluation Center provides evidence-based reports on health care technology assessment in the areas of diagnosis, treatment, management, and prevention of disease.</td>
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<tr>
<td>F1000Posters 1</td>
<td>Open repository for posters and slides from scientific conferences</td>
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<tr>
<td>FDA Advisory Committee Alerts 12</td>
<td>Email notification from FDA when advisory committees are scheduled to discuss drugs and devices</td>
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<tr>
<td>FDA Approval Alerts 12</td>
<td>Email notification from FDA when drugs, devices, and biologics and food additives are approved</td>
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<td>FDA Device Daily Bulletin 12</td>
<td>Daily e-newsletter reporting on FDA regulatory, legislative, and business news developments in the medical device industry</td>
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<tr>
<td>FDA Drug Daily Bulletin 12</td>
<td>Daily e-newsletter reporting on regulatory, legislative, and business news developments in the pharmaceutical industry</td>
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<td>FDA Orphan Drug Designation Database 12</td>
<td>Database of drugs that have received orphan drug status</td>
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<tr>
<td>Fierce Markets Network 2, 4, 8, 10</td>
<td>Series of daily email newsletters on a range of health care topics, including biotechnology, devices, pharmaceutical, health information technology, and reimbursement issues</td>
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<tr>
<td>Forbes 2, 4, 8</td>
<td>Biweekly business news magazine</td>
<td>x</td>
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<td>x</td>
<td>x</td>
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<tr>
<td>Fortune 2, 4, 8</td>
<td>Biweekly news magazine focusing on political, economic, and social issues related to business</td>
<td>x</td>
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<tr>
<td>GARD In the Spotlight</td>
<td>Press released from GARD about rare diseases</td>
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<tr>
<td>Resource Name and Type (1–12; See Key at End of Table)</td>
<td>Description</td>
<td>Biologics Biotech</td>
<td>Device</td>
<td>Drug</td>
<td>In Vitro Diagnostics</td>
<td>Procedure/Therapy</td>
<td>Process</td>
<td>Off-label Use</td>
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<tr>
<td>Gene Therapy Net 2, 3, 4, 8, 12</td>
<td>Information resource for basic and clinical research in gene therapy, cell therapy, and genetic vaccines for patients and professionals interested in gene therapy</td>
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<td>GenomeWeb 2, 3, 4, 8</td>
<td>Independent online news organization covering the scientific and economic ecosystem spurred by the advent of high-throughput genome sequencing</td>
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<tr>
<td>Google News Mental Health 2, 4</td>
<td>Daily feed of mental health coverage from multiple sources</td>
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<tr>
<td>Health Affairs 1, 4, 5, 6</td>
<td>Monthly peer reviewed journal of health policy thought and research exploring health policy issues of concern both domestically and internationally</td>
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<tr>
<td>HealthCare: The Journal of Delivery Science and Innovation 1</td>
<td>Journal promoting cutting-edge research on innovation in health care delivery, including improvements in systems, processes, management, and applied information technology</td>
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<tr>
<td>Health Leaders Media 2, 5, 8</td>
<td>Information on management trends, innovations, market strategies, and organizational development for health care executives and professionals</td>
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<td>Healthcare IT News 2, 4, 8, 10</td>
<td>Monthly newsletter includes new technologies, IT strategies and tactics, statutory and regulatory issues, and provider and vendor updates; published in partnership with Healthcare Information and Management Systems Society</td>
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<tr>
<td>Histiocytosis Society Rare Disease Feed 2, 3</td>
<td>Daily feed of rare disease coverage from multiple sources</td>
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<tr>
<td>Imaging Economics 2, 3, 4, 8</td>
<td>Monthly magazine providing information on the development, diffusion, acquisition, and utilization of imaging technology to radiologists, radiology administrators, and executives</td>
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<td>iMedicalApps 4, 6, 8</td>
<td>Independent online medical publication written by a team of physicians and medical students who provide commentary and reviews of mobile medical technology and applications</td>
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<tr>
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<td>In Vitro Diagnostics</td>
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<tr>
<td>Institute for Healthcare Improvement 1, 4</td>
<td>Independent not-for-profit organization focusing on motivating and building the will for change, identifying and testing new models of care in partnership with both patients and health care professionals, and ensuring the broadest possible adoption of best practices and effective innovations</td>
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<tr>
<td>International Journal of Healthcare Technology and Management 1, 11</td>
<td>Bimonthly, peer reviewed journal covering technology assessment and management, innovation, and new product development</td>
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<tr>
<td>JAMA 1, 2, 4, 5</td>
<td>Weekly, peer reviewed journal covering all areas of medical research</td>
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<tr>
<td>JAMA Internal Medicine 1, 4, 5, 7, 9</td>
<td>Bimonthly, peer reviewed journal from the American Medical Association; publishes original medical research targeted to internists practicing as generalists or medical subspecialists</td>
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<tr>
<td>Journal of Alzheimer's Disease News 2, 4</td>
<td>International multidisciplinary journal to facilitate progress in understanding the etiology, pathogenesis, epidemiology, genetics, behavior, treatment, and psychology of Alzheimer’s disease</td>
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<tr>
<td>Journal of Clinical Psychiatry 1, 2</td>
<td>Peer reviewed journal publishing medical research in all areas relating to mental and behavioral health; also covers newest advances in the diagnosis and treatment of mental disorders</td>
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<tr>
<td>Journal of Health Services Research and Policy 1, 4</td>
<td>Peer reviewed journal covering the ideas, policies, and decisions shaping health services throughout the world; examines current issues in health care policy and research</td>
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<tr>
<td>Journal of Medical Devices 1, 2</td>
<td>Quarterly peer reviewed journal focusing on applied research and the development of new medical devices that improve diagnostic interventional and therapeutic treatments. Provides special coverage of novel devices that allow new surgical strategies; new methods of drug delivery; or possible reductions in the complexity, cost, or adverse results of health care</td>
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<tr>
<td>Journal of Pediatrics 1</td>
<td>International, peer reviewed journal of pediatric research; geared toward clinicians; covers the latest developments in pediatric medicine</td>
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<tr>
<td>Resource Name and Type (1–12; See Key at End of Table)</td>
<td>Description</td>
<td>Biologics Biotech</td>
<td>Device</td>
<td>Drug</td>
<td>In Vitro Diagnostics</td>
<td>Procedure/Therapy</td>
<td>Process</td>
<td>Off-label Use</td>
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<tr>
<td><strong>Journal of Psychiatric Research</strong>&lt;br&gt;1, 2, 4</td>
<td>Journal dedicated to timely studies in 4 areas: clinical studies, basic studies, growing application of clinical laboratory techniques in psychiatry, and advances in basic and clinical research methodology</td>
<td></td>
<td></td>
<td>x</td>
<td></td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Kaiser Family Foundation publications</strong>&lt;br&gt;1, 2, 4, 5</td>
<td>A leader in health policy and communications, the Kaiser Family Foundation is a nonprofit, private operating foundation focusing on the major health care issues facing the United States, as well as the US’ role in global health policy. Kaiser develops and runs its own research and communications programs, sometimes in partnership with other nonprofit research organizations or major media companies.</td>
<td></td>
<td>x</td>
<td></td>
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<td>x</td>
<td></td>
</tr>
<tr>
<td><strong>Lancet</strong>&lt;br&gt;1, 4, 5</td>
<td>Weekly, peer reviewed journal that publishes clinical trials results, research, and analysis in all fields of medical research</td>
<td></td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td><strong>MDLinx</strong>&lt;br&gt;1, 2, 11</td>
<td>Daily aggregate of medical articles and research from peer reviewed journals and news media</td>
<td></td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td><strong>Med Tech Insight</strong>&lt;br&gt;2, 4</td>
<td>Newsletter providing business intelligence and insight in the medical technology industry; analyzes current markets and future trends in the industry, including technologies, clinical applications, key players, and start-up companies</td>
<td></td>
<td></td>
<td>x</td>
<td></td>
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</tr>
<tr>
<td><strong>MedGadget</strong>&lt;br&gt;2, 3, 4, 6, 8</td>
<td>Internet journal of emerging medical technologies</td>
<td></td>
<td></td>
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</tr>
<tr>
<td><strong>Medical Device Daily</strong>&lt;br&gt;1, 2, 4, 8</td>
<td>Covers new product developments, company news, regulatory activity, legislative actions, strategic alliances, sales and mergers, and market updates</td>
<td></td>
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</tr>
<tr>
<td><strong>Medical Xpress</strong>&lt;br&gt;2, 3</td>
<td>Web-based medical and health news service that features the most comprehensive coverage in several fields</td>
<td></td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td><strong>MedicalNet Rare Disease News</strong>&lt;br&gt;2, 4</td>
<td>Daily feed of rare disease coverage from multiple sources</td>
<td></td>
<td></td>
<td></td>
<td>x</td>
<td></td>
<td></td>
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</tr>
<tr>
<td><strong>Medics 4 Rare Disease</strong>&lt;br&gt;2, 4</td>
<td>Advocacy group for educating medical professionals about rare disease topics</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>Resource Name and Type</td>
<td>Description</td>
<td>Biologics</td>
<td>Device</td>
<td>Drug</td>
<td>In Vitro Diagnostics</td>
<td>Procedure/Therapy</td>
<td>Process</td>
<td>Off-label Use</td>
</tr>
<tr>
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</tr>
<tr>
<td>MedPage Today [includes conference coverage] 2, 4, 5, 6, 9, 11</td>
<td>Targeted to physicians; provides a clinical perspective on breaking medical news read by consumers. Codeveloped by MedPage Today and the University of Pennsylvania School of Medicine, Office of Continuing Medical Education, each article alerts clinicians to breaking medical news, with summaries and actionable information enabling them to better understand the implications.</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Medscape 1, 2, 9, 11</td>
<td>Resource for physicians: medical journal articles, MEDLINE, medical news, major conference coverage, and drug information</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>MedTech Insight 2, 4</td>
<td>Newsletter providing business intelligence and insight in the medical technology industry; analyzes current markets and future trends in the industry, including technologies, clinical applications, key players, and start-up companies</td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MIT Technology Review 2, 4, 5, 6, 7, 8</td>
<td>Magazine providing information on emerging technologies and impact on business and society</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>MobiHealthNews 2, 4</td>
<td>Digital health’s publication of record covering breaking news and contextualizing the trends for health care innovators</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
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<td>X</td>
</tr>
<tr>
<td>Nature.com Dementia/Alzheimer’s 1, 2</td>
<td>Coverage of breaking science from a major scientific journal, in the fields of Alzheimer’s disease and dementia</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
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<td>X</td>
</tr>
<tr>
<td>Neurology 1, 4, 5</td>
<td>Journal of the American Academy of Neurology providing peer reviewed articles, editorials, and reviews for clinical neurologists</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X</td>
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<td></td>
<td>X</td>
</tr>
<tr>
<td>Neurosurgery 1, 2</td>
<td>Official Journal of the Congress of Neurological Surgeons reporting on research in neurosurgery and the latest science, technology, and medicine</td>
<td></td>
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<td>X</td>
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</tr>
<tr>
<td>New England Journal of Medicine 1, 2, 4, 5, 7, 9</td>
<td>Peer reviewed medical journal featuring current research information, reviews, and articles for biomedical science, internal medicine, and clinical practice</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X</td>
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<td>X</td>
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<tr>
<td>The New York Times 2, 3, 4, 5, 7</td>
<td>Comprehensive health information on newly emerging technologies</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X</td>
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<td></td>
<td>X</td>
</tr>
<tr>
<td>Resource Name and Type (1–12; See Key at End of Table)</td>
<td>Description</td>
<td>Biologics Biotech</td>
<td>Device</td>
<td>Drug</td>
<td>In Vitro Diagnostics</td>
<td>Procedure/Therapy</td>
<td>Process</td>
<td>Off-label Use</td>
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<tr>
<td>New FDA Drug &amp; Device Approvals</td>
<td>Breaking news on new FDA drug and device approvals</td>
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<tr>
<td>NORD News</td>
<td>NORD coverage of new developments in rare diseases</td>
<td>X</td>
<td>X</td>
<td></td>
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<td>X</td>
</tr>
<tr>
<td>Oncology</td>
<td>Peer reviewed research journal to advance clinically relevant knowledge of cancer and improve the outcome of prevention, diagnosis, and treatment; publishes clinical studies, translational laboratory findings, mini-reviews, and controversial topics in oncology; also focuses on rapid peer review and subsequent publication of short reports of phase 1 and 2 clinical cancer trials</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Pharmacy &amp; Therapeutics</td>
<td>Journal for pharmacy and therapeutics decision makers</td>
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<tr>
<td>Pharmaceutical Business Review</td>
<td>Pharmaceutical industry news</td>
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<td>X</td>
</tr>
<tr>
<td>Pipelinereview.com</td>
<td>Provides business information on biologics regarding R&amp;D, markets, sales, technologies, and competitors</td>
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<td>X</td>
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<tr>
<td>PLoS Medicine</td>
<td>Peer reviewed open-access journal that publishes medical research</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>PR Newswire</td>
<td>Provides business information on biologics regarding R&amp;D, markets, sales, technologies, and competitors</td>
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<td></td>
<td></td>
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<td></td>
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<tr>
<td>Psychiatric News</td>
<td>Bimonthly newspaper of the American Psychiatric Association (APA); the principal and official means of communication between APA and its members about policies, politics, and legislative and judicial issues plus clinical and research news affecting psychiatry</td>
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<tr>
<td>Psychiatric Times</td>
<td>Monthly psychiatric magazine from UBM Media</td>
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<tr>
<td>Radiotherapy and Oncology</td>
<td>Peer reviewed journal covering radiation oncology</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>RARE Daily</td>
<td>Daily news and articles from Global Genes, a non-profit 501(c)(3) corporation advocating for rare disease globally</td>
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<tr>
<td>Robert Wood Johnson Foundation</td>
<td>Philanthropy that funds and produces knowledge, new ideas, and expertise to improve health and health care</td>
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<td></td>
<td>X</td>
</tr>
<tr>
<td>Resource Name and Type (1–12; See Key at End of Table)</td>
<td>Description</td>
<td>Biologics</td>
<td>Device</td>
<td>Drug</td>
<td>In Vitro Diagnostics</td>
<td>Procedure/Therapy</td>
<td>Process</td>
<td>Off-label Use</td>
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<tr>
<td>Science Daily Alzheimer’s News 2, 4</td>
<td>Daily news aggregation service about Alzheimer’s Disease symptoms, such as memory loss and senile dementia, and the treatments and causes</td>
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<tr>
<td>Science News Mental Health News 2, 4</td>
<td>Current news on clinical depression, schizophrenia, bipolar disorder, and ADHD</td>
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<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>STAT 2, 4, 5</td>
<td>Original reporting on health, medicine, and scientific discovery</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Targeted Oncology 2, 4</td>
<td>Provides news, videos, and reviews on the rapidly evolving world of targeted therapies and immunotherapy for oncologists treating patients</td>
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<td></td>
</tr>
<tr>
<td>Telemedicine and e-Health 1, 2, 8</td>
<td>Covers all aspects of research dealing with clinical effectiveness, efficacy, and safety of telemedicine and its effects on quality, cost, and accessibility of care</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>UroToday 1, 2</td>
<td>Online newsletter that aggregates original research and news about developments in various urinary cancers and diseases</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wall Street Journal 2, 4, 5, 6, 7</td>
<td>Comprehensive health information on newly emerging technologies</td>
<td>X</td>
<td>X</td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>Washington Post 2, 4, 5, 6, 7</td>
<td>Comprehensive health information on newly emerging technologies</td>
<td>X</td>
<td>X</td>
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</tbody>
</table>

Key to Resource Type:
1: Original research and scientific reviews
2: News
3: Press releases
4: Commentary
5: Editorial
6: Blogs
7: Letters
8: Product information
9: Education/continuing medical education (CME)
10: Coverage decisions
11: Conference reports
12: Regulatory
### Table A.2. Databases to Be Searched

<table>
<thead>
<tr>
<th>Resource</th>
<th>Biologics/ Biotechnology</th>
<th>Devices</th>
<th>Drugs</th>
<th>In Vitro Diagnostics</th>
<th>Procedures</th>
<th>Process</th>
</tr>
</thead>
<tbody>
<tr>
<td>EMBASE</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>EuroScan</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Healthcare News, current (LexisNexis)</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>PR Newswire</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>PsycINFO</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>PubMed/Medline</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

### Table A.3. Example of an Initial EMBASE Filter for Broad Exploratory Search of a Priority Area

<table>
<thead>
<tr>
<th>Set Number</th>
<th>Concept</th>
<th>Search Statement</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Stroke (part of cardiovascular priority area)</td>
<td>*stroke/ or (stroke or cerebrovascular accident or brain attack).ti.</td>
</tr>
<tr>
<td>2</td>
<td>Publication types likely to yield content for Horizon Scanning System</td>
<td>conference paper/ or feasibility study/ or preliminary communication/ or trend study/</td>
</tr>
<tr>
<td>3</td>
<td>Keywords likely to yield content for Horizon Scanning System</td>
<td>Advances.ti. or development$.ti. or emerging or feasibility or (first adj2 class) or (first adj2 man) or future or horizon or innovative or investigational or new.ti. or novel or pilot or pipeline or (proof adj2 principle) or translational or trend$</td>
</tr>
<tr>
<td>4</td>
<td>Combine sets</td>
<td>1 and (2 or 3)</td>
</tr>
<tr>
<td>5</td>
<td>Limit</td>
<td>4 and (human/ or humans/)</td>
</tr>
</tbody>
</table>

### Table A.4. Initial Leads List by PCORI Priority Area

<table>
<thead>
<tr>
<th>Leads List</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Alzheimer’s disease and other dementias</td>
<td>Examples of subcategories: Alzheimer’s disease, Creutzfeldt-Jakob disease, Lewy body dementia, Parkinson’s disease dementia, vascular dementia</td>
</tr>
<tr>
<td>Cancer</td>
<td>Examples of subcategories: biliary, breast, colon, kidney, liver, lung, ovarian, pancreas</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>Examples of subcategories: aneurysms, arrhythmias, coronary artery disease, heart failure, peripheral vascular disorders, stroke, varicose veins</td>
</tr>
<tr>
<td>Mental and behavioral health</td>
<td>Examples of subcategories: anxiety disorders, bipolar disorder, major depressive disorder, eating disorders, obsessive compulsive disorder, posttraumatic stress disorder, schizophrenia, substance abuse</td>
</tr>
<tr>
<td>Rare diseases</td>
<td></td>
</tr>
<tr>
<td>Unclassified</td>
<td></td>
</tr>
</tbody>
</table>
Appendix B. Horizon Scanning Structured Expert Comment Form

[Topic Title and Unique Identifying Number] (Each form is for a specific topic)

All fields denoted with an asterisk * must be completed in order to submit this form.

**COMMENTER'S CONTACT INFORMATION**

- Name*
- Job title (if applicable)*
- Academic, professional, and manufacturer affiliations*
- Preferred mailing address*
- Email address*
- Telephone*
- Fax
- Best times to reach you

**CONFLICTS OF INTEREST DISCLOSURE**

Please disclose below any potential intellectual or financial conflicts of interest, such as research in progress, consulting arrangements, or financial involvements with companies related to technologies, services, or programs evaluated in this draft.*

Do you consult for developers or manufacturers that do or would compete with this intervention?*

- Yes
- No

If yes, please describe the nature of your consultation below.

**HORIZON SCANNING TOPIC COMMENT FORM FOR RESEARCH AND HEALTH CARE PROFESSIONALS**

Please use the guidance below to rate the disruption potential of [topic title] relative to the current standard of care for each of the parameters described. Please provide your rationales for each rating. These parameters are intended to serve as anchoring points for considering the overall potential impact of the intervention or program. Your rationale will provide critical perspectives.

1. For [Horizon Scanning topic, ####], Potential to Improve Patient Outcomes/Quality of Life/Overall Health*

Consider the scientific and/or clinical validity of the developer’s claims and purported benefits for [Horizon Scanning topic]. Are the claims sound? Do you think the underlying theory/concept and the preliminary data reported by investigators thus far support the claim? How convinced are you about its potential to improve patient outcomes? What gaps between the theory or claims and data concern you the most? Provide your rationale.*

<table>
<thead>
<tr>
<th>1</th>
<th>None</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Small</td>
</tr>
<tr>
<td>3</td>
<td>Moderate</td>
</tr>
<tr>
<td>4</td>
<td>Large</td>
</tr>
</tbody>
</table>

Rationale:*
2. **For [Horizon Scanning topic, ####], Potential to Disrupt Health Disparities**
   Do you think this intervention could potentially affect health disparities? We define disparity as a climate in the health care system that creates differences in access to, use of, and quality of care such that it affects health status or patient-oriented health outcomes. In what ways, for example, would it increase or decrease disparities and access?*

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>Small</td>
<td>Moderate</td>
<td>Large</td>
</tr>
</tbody>
</table>

   **Rationale:**

3. **For [Horizon Scanning topic, ####], Potential to Disrupt the Health Care Delivery System**
   What potential do you think [Horizon Scanning topic] has to disrupt how patients are managed and how clinicians and health systems approach the condition/disease/problem? Issues to consider include care process changes when it is implemented; length of patient stay; numbers of patients that can be treated; amount of care that needs to be delivered; amount of care that can be avoided; shift in care setting from inpatient to outpatient or to home care or one department to another; change in infrastructure needs, such as physical resources (eg, facility expansion or contraction, impact on use of shared resources within a facility or health system, capital equipment acquisition or obsolescence, expenditures or savings) and staffing resources (eg, increases/decreases, staffing mix required, patient throughput handled by staff). Provide your rationale.*

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   **Rationale:**

4. **For [Horizon Scanning topic, ####], Potential to Disrupt the Current Paradigm of Patient Care**
   Consider factors that could affect the way patients currently receive care for this disease or condition [Horizon Scanning topic]. Please place a check by each factor that could disrupt the current paradigm of care:
   - Clinician convenience/ease of use
   - Patient convenience/ease of use
   - Clinician learning curve required to use it
   - Patient learning curve required to use it
   - Clinician ease of acquisition
   - Patient ease of acquisition
   - Less invasive
   - Physical and mental capacity required of the patient for use
   - Anticipated side effects, risks, adverse events

   Please describe any potential controversies you foresee [Horizon Scanning topic] causing or its disruption potential. Provide your rationale.*

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   **Rationale:**

5. For [Horizon Scanning topic, ####], Potential Disruption to Health Care Costs*
How might [Horizon Scanning topic] disrupt costs of care for the intended patients and health care system? Please note how you expect costs to change and for whom (eg, patients, payers, health care facilities). Do you anticipate that any of the potential changes in cost would generate controversy? What kind of controversy? Provide your rationale.*

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Rationale:* 

6. For [Horizon Scanning topic, ####], Overall Disruption Potential*
Given your considerations about all the parameters you have responded to, what do you think is the overall potential of [Horizon Scanning topic] to disrupt the current standard of care paradigm? Provide your rationale.*

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Rationale:* 

Additional Comments (please limit to 1000 characters):

Note: All fields denoted with * must be completed in order to submit this form. If the form does not advance to a “confirmation page” when the “Submit” button is clicked, please scroll up and complete any remaining blank fields indicated by “response required” text.
Appendix C. Horizon Scanning Structured Patient/Patient Representative Comment Form

[to be evaluated for reading level/acceptability and revised as necessary]

[Topic Title and Unique Identifying Number] (Each form is for a specific topic)

All fields denoted with an asterisk * must be completed in order to submit this form.

**COMMENTER'S CONTACT INFORMATION**
- Name*
- Email address*
- Telephone
- Mailing address
- Preferred form of contact
- Best times to reach you
- Organization (if any)

**CONFLICTS OF INTEREST DISCLOSURE**
Please disclose below any potential intellectual or financial conflicts of interest, such as involvement in research studies, consulting arrangements, or financial involvements with companies related to the treatment evaluated in this form. If none, write “None.”*

Do you consult for developers or manufacturers that do or would compete with this treatment?

Yes  No

If yes, please describe the nature of your consultation below.

**HORIZON SCANNING TOPIC COMMENT FORM FOR PATIENTS AND PATIENT REPRESENTATIVES**
Please rate the potential of [Horizon Scanning topic, ####] to change health care for each of the 6 areas described below, each of which described important points that influence the overall potential impact of the treatment. Please provide an explanation for each of your ratings. Your explanations will provide valuable perspectives.

**PLEASE NOTE:** We are especially interested in your comments underpinning each score. These comments inform our thinking as we prepare reports for the Patient-Centered Outcomes Research Institute (PCORI) designating which topics in the Health Care Horizon Scanning System commenters believe could have the highest potential to change health care. Topics designated as having high potential for change will become inputs into decision making about PCORI’s investments in future comparative-effectiveness research projects.
1. **Potential to improve patient outcomes, quality of life, and overall health**
Consider the manufacturer’s claims for this treatment. What potential do you think this treatment has to improve health outcomes for patients (ie, quality of life)? What gaps between the claims and data concern you the most? Provide your rating and explanation.*

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Explanation:* 

2. **Potential to affect health disparities**
Disparities in the health care system create differences in access to, use of, and quality of care that affect the health status of patients. What potential do you think this treatment has to affect health disparities? In what ways would it increase or decrease disparities (ie, access to care)? Provide your rating and explanation.*

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Explanation:* 

3. **Potential to change the health care delivery system**
Consider how this treatment could affect the delivery of care for this condition or disease. For example:

- The way doctors or other health care providers approach the disease, condition, or problem
- The number of patients that can be treated
- The amount of time patients spend receiving care
- The level of care delivered
- The process of delivering care
- The change in care setting (ie, inpatient to outpatient)
- The number of staff needed to deliver care

What potential do you think this treatment has to change how patients are managed in the health care system? Provide your rating and explanation.*

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Explanation:*
4. **Potential to change the current pattern of patient care***

Consider factors that could affect the way patients currently receive care for this disease or condition. Please place a check by each factor that could change the way that health care is delivered:

- The convenience/ease of use for the doctor or other health care provider
- The convenience/ease of use for the patient
- How hard it will be for the doctor or other health care provider to learn to use it
- How hard it will be for the patient to learn to use it
- How likely a doctor or other health care provider will be to use it
- How likely a patient will be to use it
- The impact it will have on the patient’s body
- The ability of the patient to use it
- The anticipated side effects, risks, and adverse events

Rate this treatment’s potential for changing the care is delivered. Provide your rationale, and please describe any potential controversies you foresee [Horizon Scanning topic] causing.*

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Explanation:*  

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5. **Potential to change health care costs***

Rate this treatment’s potential to change costs of care for the intended patients, insurance providers, and the health care system. Would any potential changes in costs generate controversy? Provide your explanation.*

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Rationale:*  

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6. **Overall potential to change health care***

Given your responses, what do you think is the overall potential of this treatment to change the current standard of care for this condition or disease? Provide your overall rating and explanation.*

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Rationale:*  

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**Additional Comments (please limit to 1000 characters):**

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Appendix D. Horizon Scanning Trend Survey Form

1. In which of the following areas might the trend cause disruption (positive or negative) in the United States? Select all that apply. For each area you select, indicate how disruptive you think the trend will be in that area (slightly disruptive, moderately disruptive, highly disruptive).
   - Patient outcomes
   - Access to care
   - Health disparities
   - Care delivery
   - Staffing
   - Costs
   - Other (please specify)

2. (If commenter selected at least one item from question)* Consider your selections above and their combined impacts. How disruptive (positively or negatively) do you think the trend might be overall to health care in the United States?
   1) Not disruptive
   2) Slightly disruptive
   3) Moderately disruptive
   4) Highly disruptive

3. (If commenter selected 2, 3, or 4 for question 2)* How soon would you expect this disruption to occur?
   1) 4 or more years from now
   2) 2 to 4 years from now
   3) 0 to 2 years from now
   4) Occurring now

4. (If commenter selected 1, 2, or 3 for question 3)* How likely is it that this disruption will occur?
   1) Highly unlikely
   2) Somewhat unlikely
   3) Somewhat likely
   4) Highly likely

5. In the box below, provide a brief rationale for your answers above. Include a discussion of threats or opportunities the trend might pose. If you do not believe this trend will be disruptive, please explain. (1000 characters or fewer)

* These questions are only displayed if the specified conditions are met.