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PCORI HEALTH CARE HORIZON SCANNING SYSTEM

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Horizon Scanning Protocol and Operations Manual COVID-19 Supplement

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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 potential impact of interventions. Citation of the source is appreciated.

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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.

This document supplements the *PCORI HCHSS Protocol and Operations Manual* by describing ECRI's horizon scanning process related to the COVID-19 pandemic, which arose in late 2019.

Horizon scanning involves 2 processes. The first is identifying and monitoring 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 is analyzing 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 COVID-19 supplement is not to predict future utilization and costs of any health care innovation; rather, it is intended to help inform and guide planning and prioritization of research resources.

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.

Contents

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—both positive and negative—in areas such as access to care, care delivery processes, care settings, costs of care, current treatment models or paradigms, health disparities, health care infrastructure, and patient health outcomes. Some 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.

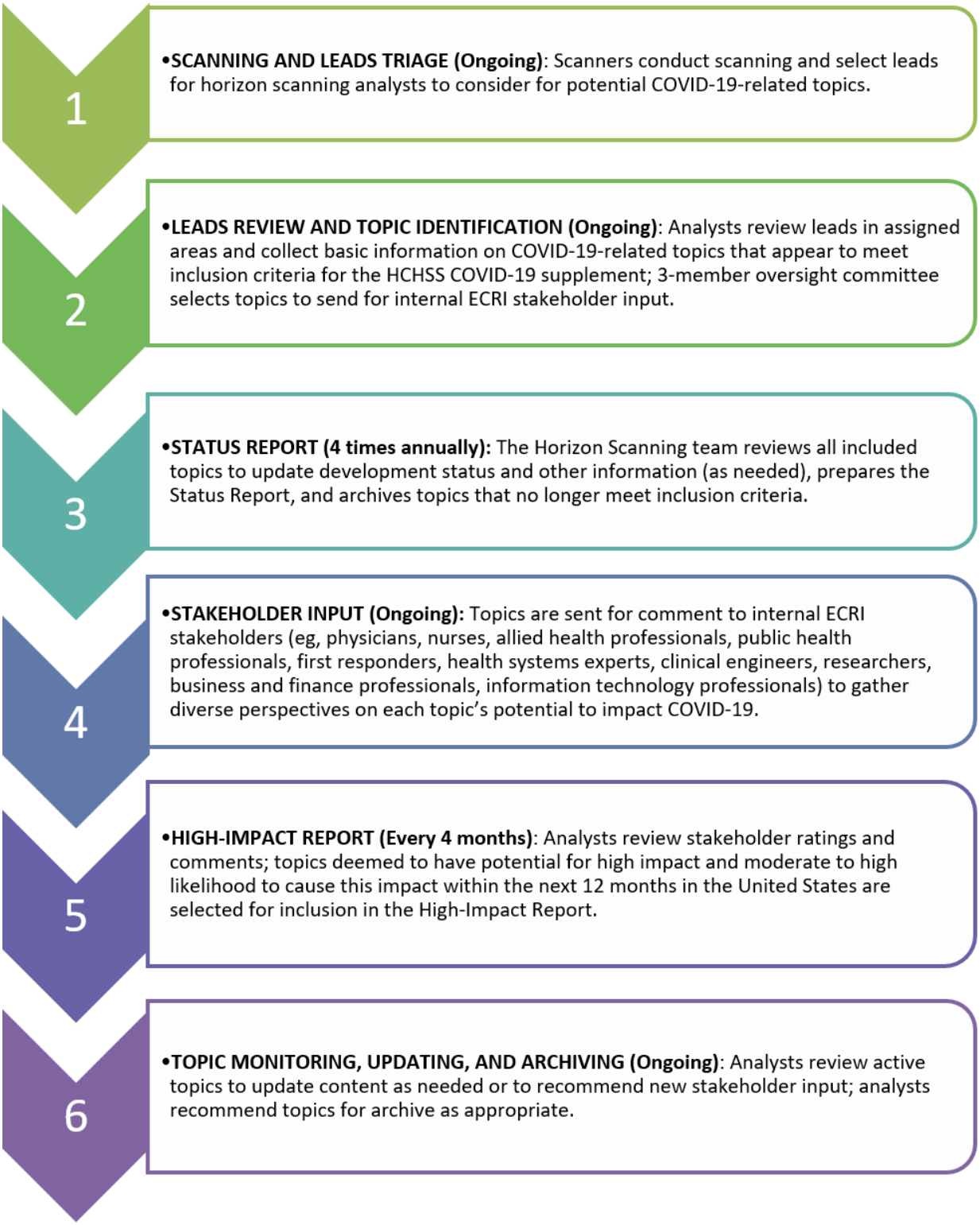
In December 2018, the PCORI Health Care Horizon Scanning System (HCHSS) was implemented to provide PCORI with a systematic process to identify and monitor technologies and innovations in health care that are in PCORI's priority areas of interest and to create an inventory of interventions that have the 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.

Initially, PCORI defined the HCHSS 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.

In late 2019, the COVID-19 pandemic created a fast-moving, widespread public health crisis. In May 2020, PCORI expanded its HCHSS to elucidate the landscape of potentially impactful applications for COVID-19. This HCHSS COVID-19 supplement will scan for, identify, monitor, and report on emerging and available COVID-19-related treatments, diagnostics, preventive measures, management strategies, and systems changes with high potential to impact patient outcomes—for individuals and populations—in the United States within the next 12 months.

This document outlines the basic protocol and decision processes used to scan for COVID-19-related leads, select topics for monitoring, and identify interventions and solutions in each content area (ie, treatments, vaccines and prophylaxis, identifiable risk factors and prognostic indicators, systems and management, devices, and screening and diagnostics) with high potential for impact. Figure 1 depicts an overview of these processes.

Figure 1. PCORI Health Care Horizon Scanning System COVID-19 Supplement Process Overview



PCORI Health Care Horizon Scanning System Supplementary Process for COVID-19

In this section, we describe the overall process and discrete steps involved in operating and maintaining the PCORI HCHSS COVID-19 supplement.

Step 1. Scanning and Lead Selection

Led by the horizon scanning knowledge manager, broad scanning is performed by medical librarians and research assistants (also collectively called scanners), who funnel leads to a team of horizon scanning analysts. As related leads aggregate, analysts develop specific topics (see step 2).

For the HCHSS COVID-19 supplement, scanning captures COVID-19-related leads for treatments, diagnostics, preventive measures, management strategies, and systems changes with potential to impact patient outcomes—for individuals and populations—in the United States within the next 12 months.

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. They download items of interest in electronic format and post them to the leads database, then classify the leads by clinical areas and clinical conditions, selecting the appropriate values from dropdown lists. See Table A.1. for a list of scanning sources most relevant to COVID-19. Other COVID-19 leads will also emerge from and be captured from the broader set of sources detailed in the *PCORI HCHSS Protocol and Operations Manual*.

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. For example, because a significant margin of error exists in predicting a topic's potential time to impact, scanners capture leads pertaining to topics with apparent potential for impact within 24 months of the date of scanning. Analysts, who possess greater subject area knowledge than scanners, subsequently review each lead to determine whether a topic's potential for impact falls within 12 months of the date of scanning (see step 2).

Several sets of questions inform scanners' decision making about whether a lead appears to represent an intervention that is novel, innovative, or relevant and that may have impact in one or more areas of health care, such as patient health, health care processes, delivery, cost, care settings, or disparities. These questions are listed below.

Questions Considered About Treatments

- Is this a new pharmaceutical, antiviral, biologic, cell therapy, or other treatment that is being developed for potential diffusion into the US health care system AND
    - is in late-phase (phase III or IV) clinical development;

    - is in phase II clinical development with orphan, breakthrough, or fast-track status designation by the US Food and Drug Administration (FDA); or
    - has been granted Emergency Use Authorization (EUA) by FDA?
- Is this an existing treatment that
    - could be used off label,
    - is being actively repurposed, or
    - has been granted EUA by FDA?
- Is this a novel or newly deployed development platform intended to rapidly produce COVID-19 treatments?

Questions Considered About Vaccines and Prophylaxis

- Is this a new vaccine that is being developed for potential diffusion into the US health care system AND
    - is in late-phase (phase III or IV) clinical development;
    - is in phase II clinical development with orphan, breakthrough, or fast-track status designation by FDA; or
    - has been granted EUA by FDA?
- Is this intervention being considered to inhibit coronavirus infection either before or after exposure?

Questions Considered About Identifiable Risk Factors

- Is this an emerging risk factor for COVID-19 disease
    - modification,
    - comorbid complications,
    - prognosis,
    - postnatal outcomes, or
    - other impact on disease progression?

Questions Considered About Systems and Management

- Is this a systems-level intervention that could be applied to the US health care system's
    - treatment or management capacity,
    - treatment or management processes,
    - treatment or management delivery methods,
    - treatment or management policies,
    - supply chain (eg, shortages of drugs or equipment), or
    - other consequences of COVID-19 to the health care system?

Questions Considered About Devices

- Is this a new device that is being developed for potential diffusion into the US health care system AND
    - is in late-phase (phase III or IV) clinical development,
    - is in phase II clinical development with breakthrough or fast-track status designation by FDA, or
    - has been granted EUA by FDA?
- Is this an existing device that
    - could be used off label,
    - is being actively repurposed or modified, or

    - has been granted EUA by the FDA?
- Is this device being manufactured by an alternative industry specifically for COVID-19 use?

Questions Considered About Screening and Diagnostics

- Is this a screening method that could be implemented in the US health care system?
- Is this a new diagnostic or screening test for COVID-19 that
    - has been granted EUA by FDA;
    - can be implemented under the Centers for Medicare & Medicaid Services Clinical Laboratory Improvement Amendments certification; or
    - has received or might receive FDA Premarket Approval, 510(k) clearance, or de novo approval?
- Is this an existing diagnostic device or modality that is growing in use for COVID-19?
- Is this a novel diagnostic or screening device for COVID-19?

Step 2. Leads Review and Topic Identification

Scanners collect COVID-19-related leads (as described above) from broad scanning and enter them into the leads database, categorize them according to content area (ie, treatments, vaccines and prophylaxis, identifiable risk factors and prognostic indicators, systems and management, devices, and screening and diagnostics) and subcategory, and link them, if applicable, to existing topics in the COVID-19 topics database. A research assistant assigns each lead to a horizon scanning analyst for review.

If the analyst determines that a lead or set of leads addresses a topic appropriate for the COVID-19 HCHSS supplement, the analyst asks the following questions:

1. Does the topic pertain to COVID-19-related treatments, diagnostics, preventive measures, management strategies, or systems changes?
2. Does the topic have potential for high impact relative to COVID-19-related health care and/or public health efforts in the United States?
3. Is the topic's impact likely to occur within the next 12 months?

If the analyst answers "yes" to these 3 questions, then she or he creates and populates a new entry in the COVID-19 topics database. To populate the newly created topic record, the analyst enters a title and a description of the topic and indicates expected areas of impact and potential outcomes. The analyst then enters a brief rationale stating the case for proposing the topic for inclusion in the HCHSS COVID-19 supplement.

To expedite the content development and delivery process, we employ an abbreviated nomination process to select topics for entry into the system. Each topic is rapidly reviewed and voted on for inclusion by a 3-member panel consisting of the PCORI HCHSS project manager, knowledge manager, and lead analyst (or senior content reviewer, if the lead analyst identified the topic). Members of the panel have 2 business days from the time of topic identification to review and vote for or against a topic's inclusion. The review and voting process is online and asynchronous. A majority vote includes or excludes a topic accordingly.

A topic selected for inclusion in the HCHSS COVID-19 supplement undergoes content review and copyediting before being activated as a summary for the stakeholder comment process (see step 3). Before content review, an analyst may request topic-specific searches to identify key additional information. The analyst then revises the topic record accordingly before submitting it for content review.

Biweekly COVID-19 Scans

Every 2 weeks, the ECRI HCHSS team creates the COVID-19 Scan, which is a vehicle to inform PCORI, in a timely manner, of important topics of interest identified during our ongoing scanning and topic identification process or through the stakeholder comment process. The Scan is 1 to 3 pages long and contains 2 sections: a briefing (up to 250 words) summarizing points of interest over the past 2 weeks, and one or more topic summaries (topic title, category, areas of potential impact, description) and brief commentary highlighting particular items of interest identified within the past 2 weeks.

Status Reports

At regular intervals (beginning July 7, 2020, then every 3 months thereafter), data for all monitored COVID-19-related topics will be exported and compiled into a Status Report. The report will include a section for each content category (ie, treatments, vaccines and prophylaxis, identifiable risk factors and prognostic indicators, systems and management, devices, and screening and diagnostics). Each section contains up to 3 tables: (1) new topics added since the last Status Report, (2) currently monitored topics, and (3) topics archived since the last Status Report. If no topics fall into a given category (ie, added, monitored, or archived), no table will be included for that category in that section. Tables for newly added and currently monitored topics will summarize information in each row, with columns for the topic title, description, areas of potential impact, potential outcomes, and the date we first identified the topic. When present, the table of archived topics will include an additional column briefly describing the reason for archiving the topic.

Step 3. Stakeholder Survey Process

Topics are posted to an online bulletin board visible to a preselected panel of internal ECRI expert stakeholders (eg, physicians, nurses, allied health professionals, public health professionals, first responders, health systems experts, clinical engineers, researchers, business and finance professionals, information technology professionals). As topics are posted, stakeholders review them and complete an accompanying survey, which elucidates the stakeholder's perspective on the topic's potential for impact relative to the COVID-19 pandemic in the United States.

The survey prompts the stakeholder to answer the following questions:

1. In which areas does this topic have potential for impact relative to COVID-19 in the United States? (Rank each answer from 1 to 4, with 1 meaning no impact and 4 meaning high impact.)
    - Patient outcomes
    - Population health

    - Clinician and/or caregiver safety
    - Health care delivery and processes
    - Health care disparities
    - Health care costs
    - Other (specify)
2. Given your selections and ratings above, what is this topic's overall potential for impact relative to COVID-19 in the United States? (Select a rating of 1 to 4 as shown below.)
    - 1: No impact
    - 2: Low impact
    - 3: Moderate impact
    - 4: High impact
3. How soon would you expect this impact? (Select a rating of 1 to 4 as shown below.)
    - 1: 2 or more years from now
    - 2: 1 to 2 years from now
    - 3: 0 to 1 year from now
    - 4: Occurring now
4. What is the likelihood that this impact will occur? (Select a rating of 1 to 4 as shown below.)
    - 1: Highly unlikely
    - 2: Somewhat unlikely
    - 3: Somewhat likely
    - 4: Highly likely
5. Provide a rationale for your selections and ratings above. Include a discussion of the impacts you expect this topic to have.

When a topic has received at least 5 completed surveys, it is eligible to be considered for inclusion in the High Impact Report (see step 4); however, the questionnaire function remains active for all topics until the High Impact Report selection process begins, allowing each member of the expert panel to comment on each topic as time permits.

Step 4. High-Impact Topic Selection and Reporting

Every 4 months, all currently monitored topics that have received at least 5 completed stakeholder surveys are considered for inclusion in the High-Impact Report. The purpose of the selection process is to identify topics that stakeholders have deemed to have potential for high impact relative to COVID-19 in the United States.

Generally, a topic that receives average (mean) ratings as follows for each of the 3 points below is selected for inclusion:

1. Overall impact: Rating of 3.2 or higher (ie, high-moderate to high impact potential)
2. Timing of impact: Rating of 2.8 or higher (ie, occurring within about 1 year)
3. Likelihood of impact: Rating of 2.8 or higher (ie, somewhat likely to highly likely)

Thresholds may be adjusted for average scores with high or low variance (ie, when stakeholder ratings show wide variation or near consensus). In addition, analysis of stakeholder comments

must generally support conclusions suggested by ratings. For topics with borderline ratings, high variance, or questionable comments, a brief review process determines inclusion or exclusion. A 3-member panel (ie, project manager, knowledge manager, and lead analyst [or alternate]) reviews ratings and comments. A vote is then taken from this panel. A majority affirmative vote selects the topic for inclusion.

Analysts may request topic-specific searches for any topic selected for inclusion in the High Impact Report. The analyst then writes a summary of the topic, including highlights, description, areas of potential impact, potential outcomes, and key stakeholder comments. An impact score based on stakeholder ratings is calculated and added to the summary.

Topic summaries are compiled into the report chapter corresponding to the topic's content area (ie, treatments, vaccines and prophylaxis, identifiable risk factors and prognostic indicators, systems and management, devices, and screening and diagnostics). The project manager reviews each topic summary and writes a chapter introduction. Each chapter is then reviewed by the senior technical reviewer and medical copyeditor.

Chapters are compiled into a single High-Impact Report. The project manager reviews the report and writes a report introduction that includes background, an overview of the horizon scanning process specific to the COVID-19 supplement, a description of the report methodology, and a reporting period summary.

Step 5. Topic Monitoring, Updating, and Archiving

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. Analysts update topics as new information arises to ensure that the content is up to date.

New information may indicate that a topic should be archived. Some possible reasons are listed below:

1. The product or intervention fails to meet endpoints in trials and product development ceases.
2. Companies' financial resources to continue development have been exhausted.
3. 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, the topic no longer addresses a significant unmet need or shows potential for impact.
4. The topic has completed stakeholder comment and ratings, and stakeholders have concluded the topic has little potential for impact relative to COVID-19 in the United States.

Appendix A. Scanning Resources for COVID-19

Table A.1. Selected Scanning Sources Most Relevant to COVID-19

Resource Name	Description	Biologics Biotech	Device	Drug	In Vitro Diagnostics	Procedure/ Therapy	Process	Off-label Use
360Dx	Emerging economic and technological trends in the clinical diagnostic market; diagnostics market and reports on regulatory, reimbursement, and policy issues				X		X	
Advances in Pharmacy ASHP Daily Briefing	Daily email briefing summarizing key medical and health care news from the previous 24 hours; targeted to health system pharmacists			X	X			
AHA Emerging Science Series	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	X	X	X	X	X		
AMIA	Daily download on the development and application of biomedical and health informatics in the support of patient care, teaching, research, and health care administration						X	
BioPharma Dive	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 and gene therapy, to drug pricing and mergers and acquisitions, to research partnerships.	X		X		X	X	X

Resource Name	Description	Biologics Biotech	Device	Drug	In Vitro Diagnostics	Procedure/ Therapy	Process	Off-label Use
BioPharma Reporter	Provides daily and weekly newsletters to subscribers. The service seeks out news and data of value to decision makers in the biopharmaceutical development and manufacturing sector.	X		X		X		
CenterWatch	Provides a variety of clinical research products and services, including a weekly rundown of current events and news	X	X	X		X		
Clinical Trials/Drug Trials News	Latest clinical trials and drug trials research from prestigious universities and journals throughout the world	X		X		X		
Clinical Trials News (Phase II) | BioSpace	Breaking news on phase II clinical trials	X	X	X		X		
Clinical Trials News (Phase III) | BioSpace	Breaking news on phase III clinical trials	X	X	X		X		
ClinicaSpace Focus	Online community for the clinical research industry. It delivers through user-friendly navigation daily news, events, company profiles, stocks, blogs, and other relevant information from the sector.	X	X	X		X		
Drugs.com – Clinical Trials	Information about recently completed clinical trials	X	X	X				
Drugs.com – FDA MedWatch Alerts	Comprehensive and up-to-date drug news for both consumers and health care professionals	X	X	X				
Drugs.com – New Drug Applications	Information about all new drug applications in the pipeline	X	X	X				
Drugs.com – New Drug Approvals	Up-to-date information on the latest FDA drug approvals; includes a list of the most recent approvals, the conditions for which the drugs are approved, and the approval history	X	X	X				

Resource Name	Description	Biologics Biotech	Device	Drug	In Vitro Diagnostics	Procedure/ Therapy	Process	Off-label Use
ECRI Institute Product Briefs and Hotline Responses	Researched responses to questions from ECRI Institute member hospitals, health plans, and other subscribing organizations about the efficacy and effectiveness of health care technologies, services, and factors affecting diffusion and implementation	X	X	X	X	X	X	X
Embase Conference Coverage	Newsfeed of abstracts indexed by Embase covering more than 4700 biomedical conferences	X	X	X	X	X		X
Emerging Infectious Diseases	Open-access, peer reviewed journal published monthly by the Centers for Disease Control and Prevention. The journal was established expressly to promote the recognition of new and reemerging infectious diseases around the world and to improve the understanding of factors involved in disease emergence, prevention, and elimination.		X			X	X	X
Endpoints (Endpoint News)	Biopharmaceutical news	X		X				
EurekAlert!	American Association for the Advancement of Science portal for press releases from universities, medical centers, journals, government agencies, corporations, and other research organizations	X	X	X	X	X	X	X
FDA Approval Alerts	Email notification from FDA when drugs, devices, and biologics and food additives are approved	X	X	X				
FDA Emergency Use Authorizations	Website that lists current and terminated Emergency Use Authorizations that make available diagnostic and therapeutic medical devices to diagnose and respond to public health emergencies		X		X			

Resource Name	Description	Biologics Biotech	Device	Drug	In Vitro Diagnostics	Procedure/ Therapy	Process	Off-label Use
FDA Device Daily Bulletin	Daily e-newsletter reporting on FDA regulatory, legislative, and business news developments in the medical device industry		X					
FDA Drug Daily Bulletin	Daily e-newsletter reporting on regulatory, legislative, and business news developments in the pharmaceutical industry			X				
GenomeWeb	Independent online news organization covering the scientific and economic ecosystem spurred by the advent of high-throughput genome sequencing	X	X		X	X		
Google	COVID-19 search on Google limited to the medRxiv domain			X		X		
iMedicalApps	Independent online medical publication written by a team of physicians and medical students who provide commentary on and reviews of mobile medical technology and applications		X			X	X	
Informa – COVID-19 Dashboard	Custom COVID-19/SARS-CoV-2 analytic portal tracking developments in real time that is updated daily by an international team of analysts	X	X	X	X	X		
Informa – Pharmaprojects	Resource comprising detailed data on all drugs in development	X		X				
Informa – Trialtrove	Resource comprising detailed data on design details, outcomes, timelines, and results for all clinical trials	X	X	X		X		
The Lancet: COVID-19 Resource Centre	Resource bringing together new COVID-19 content from across *The Lancet* journals as it is published. All of this COVID-19 content is free to access.	X		X	X	X		

Resource Name	Description	Biologics Biotech	Device	Drug	In Vitro Diagnostics	Procedure/ Therapy	Process	Off-label Use
LitCovid	Unique web system for tracking the most recent publications and literature about COVID-19	X		X	X	X		
MDLinx	Daily aggregate of medical articles and research from peer reviewed journals and news media	X	X	X	X	X	X	X
MedGadget	Internet journal of emerging medical technologies		X					X
Medical Xpress	Web-based medical and health news service that features the most comprehensive coverage in several fields	X	X	X	X	X		X
MedPage Today	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.	X	X	X	X	X	X	X
Medscape	Resource for physicians; includes medical journal articles, MEDLINE, medical news, and major conference coverage drug information	X	X	X	X	X	X	X
MIT Technology Review	Magazine providing information on emerging technologies and their impact on business and society	X	X					X
Nature	Coverage of breaking science from a major scientific multidisciplinary scientific journal	X	X	X		X		
New England Journal of Medicine	Peer reviewed medical journal featuring current research information, reviews, and articles for biomedical science, internal medicine, and clinical practice	X	X	X	X	X	X	X

Resource Name	Description	Biologics Biotech	Device	Drug	In Vitro Diagnostics	Procedure/ Therapy	Process	Off-label Use
The New York Times	Comprehensive health information on newly emerging technologies	X	X	X	X	X	X	X
PR Newswire	Provides business information on biologics regarding research and development, markets, sales, technologies, and competitors	X	X	X	X	X		X
Science	News articles, feature stories, reviews, and more in all disciplines of science	X	X	X	X	X	X	
Wall Street Journal	Comprehensive health information on newly emerging technologies	X	X	X	X	X	X	X
Washington Post	Comprehensive health information on newly emerging technologies	X	X	X	X	X	X	X
Wired	Focuses on how emerging technologies affect culture, the economy, and politics	X					X	