Advancing an agile regulatory ecosystem to respond to the rapid development of innovative technologies

M. Khair ElZarrad[1] | Aaron Y. Lee[2] | Rose Purcell[1] | Scott J. Steele[1,3]

[1]Center for Drug Evaluation and Research, U.S. Food and Drug Administration, Silver Spring, Maryland, USA

[2]Department of Ophthalmology, School of Medicine, University of Washington, Seattle, Washington, USA

[3]Clinical and Translational Science Institute and Department of Public Health Sciences, University of Rochester Medical Center, Rochester, New York, USA

Correspondence
M. Khair ElZarrad, Center for Drug Evaluation and Research, U.S. Food and Drug Administration, 10903 New Hampshire Avenue, Silver Spring, MD 20993, USA.
Email: mohammed.elzarrad@fda.hhs.gov

Present address
Rose Purcell, Takeda Pharmaceutical Company, Washington, DC, USA

Abstract

Technological advancements are dramatically changing the landscape of therapeutic development. The convergence of advances in computing power, analytical methods, artificial intelligence, novel digital health tools, and cloud-based platforms has the potential to power an exponential acceleration of evidence generation. For regulatory agencies responsible for evidence evaluation and oversight of medical products, these advances present both promises and challenges. Ultimately, realizing the translation and impact of these innovations that could potentially enhance therapeutic development and improve the health of individuals and the public will require a nimble and responsive regulatory approach. Supporting an adaptive policy-making infrastructure that is poised to address novel regulatory considerations, creating a workforce to ensure relevant expertise, and fostering more diverse collaborations with a broader group of stakeholders are steps toward the goal of modernizing the regulatory ecosystem. This article outlines approaches that can help provide the flexibility and tools needed to foster innovation, while ensuring the safety and effectiveness of medical products.

INTRODUCTION

The evolution of evidence generation supported by numerous data streams and advances in computing power, analytical methods, artificial intelligence (AI), and digital health tools, as well as the ubiquitous availability of cloud-based platforms are dramatically changing the landscape of therapeutic development. What is most unique about our era is not only the rapid advancement of discrete technologies, but the convergence of and synergies between them. This phenomenon has the potential to power an exponential acceleration of evidence generation.

Recognizing the potential of such advances, companies and other stakeholders are increasingly incorporating cutting-edge technology, including digital tools and advanced analytics, while leveraging robust platforms for information gathering, analysis, and transfer to help improve the efficiency of therapeutic development and to better customize their products to the needs of consumers. For example, AI-based applications are already being explored across the development spectrum of therapeutics from preclinical discovery to clinical trials and postmarketing surveillance. Some promising uses include predicting potential compound characteristics, identifying study

cohorts, optimizing clinical trial design and conduct, and tracking adverse events.[1-3] Other innovative technologies and methods are also evolving at a rapid pace. Those include, but are not limited to, advances in genomics, regenerative medicine, methods to manage and utilize real-world data, as well as advanced manufacturing techniques.

For regulatory agencies responsible for evidence evaluation and oversight, these advances bring both promise and challenge. Committed to helping bring safe and effective medical products to those who need them as soon as possible, public health agencies must balance facilitating innovation with providing assurance of the safe, ethical, and responsible use of new technologies. Other regulatory and standards development agencies that are addressing the diverse use of innovative technologies are confronting similar considerations. One key challenge that could face these agencies is how to attract individuals with key expertise. Another challenge is how to quickly work to educate and raise awareness of these technologies among existing staff. Individuals with certain skills may be difficult to recruit due to the competitive landscape surrounding high-demand expertise. Agencies may need to look to advance collaborations as a means to connect with experts in different fields and as an approach to encourage mutual learning.

A stable and nimble regulatory ecosystem is necessary to facilitate innovation while also safeguarding the public. This article will propose ways to establish a responsive and agile regulatory ecosystem that includes an adaptive policy-making infrastructure, effective workforce development, and the facilitation of core and essential collaborations and partnerships.

ADAPTIVE POLICY-MAKING INFRASTRUCTURE

An adaptive policy-making infrastructure is a cornerstone of a responsive and agile regulatory process. Regulatory agencies should ensure that there are groups and offices that are focused on policy development and the evaluation of innovative technologies (described hereinafter as policy offices). Policy offices should not only forecast, but also prepare for and respond frequently to provide regulatory insights on innovative technologies. A proportional risk-based approach will require an understanding of the risks and benefits of a new technology, how it evolves, including the speed at which it can evolve, and the best practices for risk and performance detection, management, and mitigation. To gain this understanding and to advance policies and regulations that are responsive to innovations, policy offices will need to consider changes not only to existing policies, but also to current processes and infrastructure used for policy development.

First, policy offices should consider the establishment of internal multidisciplinary "intelligence" teams tasked with tracking and evaluating innovative technologies. These teams, encompassing medical, scientific, engineering, public health, regulatory, ethics, policy development and analysis, and other disciplines as needed, would provide policy offices with important technological, scientific, and regulatory expertise in the development of policy approaches. The teams could assist in answering key questions, such as how to ensure that policy and guidance development takes into consideration the latest innovations in a specific sector. In an organization that conducts or funds research, intelligence teams could help inform evolving research funding priorities and determine whether current funding models should be updated and modified. For example, the teams could identify relevant research projects, including those that span multiple sectors (technology or engineering, etc.) and ways to fund them, such as through collaborative funding models with other agencies. Intelligence teams may also be responsible for performing routine analysis of existing policies and programs and evaluating their responsiveness to emerging technologies.

Second, policy offices may need to consider expanding the tools and paths available in the policy development process to make it more responsive and iterative, including a mechanism for post-deployment evaluation and frequent updating, as necessary. This process would involve formal and informal consultation with internal and external stakeholders to identify areas that should be initially included in a guidance and areas that need to be revised if the technology or its uses change. Expanding the opportunities to incorporate stakeholders' feedback iteratively throughout policy development should be considered, especially in highly impactful areas. Such consultations would benefit from being inclusive of all relevant stakeholders. This process may include the establishment of committees and working groups, workshops during guidance development, and regulatory-roundtable dialogue with internal and external stakeholders.

To be more responsive to the needs of the community, policy offices could also establish a standing or ad hoc committee(s) of interdisciplinary regulatory experts to proactively engage with external stakeholders. For example, the committee could expand outreach to stakeholders, as appropriate, to discuss stakeholders' proposals for the use of an innovative technology early in the process. These interactions could provide a valuable feedback loop through which to receive input that could be used to update guidance. These discussions may identify new gaps in current regulations that may need to be addressed by existing or new internal committees. This bidirectional communication can also provide technology developers and other stakeholders with insights into key regulatory concepts and standards that should be considered

when leveraging novel technologies in product development. An example of this approach is the Real-World Evidence Subcommittee of the Medical Policy Program and Review Committee established by the US Food and Drug Administration (FDA). This subcommittee serves as a forum to provide advisory recommendations and a platform to engage with a variety of stakeholders.[4]

Third, in addition to formal guidance, policy offices should consider utilizing the full spectrum of mechanisms to communicate with stakeholders about innovative technologies, such as white papers and proposed frameworks. These types of communication could also provide more rapid feedback loops to inform policymaking. Whereas separate from the official policy development process, "academic-style" communications developed independently by staff via editorials in peer-reviewed literature could increase awareness and provide a broader discussion of innovative technologies and topics.

EFFECTIVE WORKFORCE DEVELOPMENT

A responsive and agile regulatory process will also require effective workforce development to keep pace with the use of innovative technologies. It will be particularly important for regulatory agencies to prioritize the recruitment, hiring, and retention of staff with diverse expertise that includes relevant training and/or experience in technological areas. Technical experts will need to be part of policy development conversations to adequately assess innovative technologies and provide technical expertise and advice on their potential opportunities, limitations, and challenges.[5]

Because competing with the private sector for new talent from areas of innovative technologies can be challenging, regulatory agencies should consider the full spectrum of available mechanisms to gain access to technological expertise.[6] A talent acquisition strategy could include working with academic institutions to coordinate training opportunities for students and recent graduates, including rotations, internships, and fellowship programs, particularly in competitive areas like AI and data science. This strategy should also support cross-disciplinary collaborative training opportunities and exchange of expertise (e.g., Special Government Employees[7]) across different degree pathways (e.g., science, engineering, medicine, ethics, law, and business) to encourage cross-pollination across industry, government, academia, and other sectors.

Workforce education focused on building internal capacity and upskilling current employees could also help fill certain gaps in expertise. Intra-agency rotations (details) could be useful training opportunities for staff

detailed to work directly with technologists in other offices and centers. Interagency rotations, especially with agencies who are developing technology standards or conducting research using innovative technologies, such as the National Institute for Standards and Technology (NIST), Department of Defense (DoD), and National Institutes of Health (NIH), could provide similar benefits to agencies. In addition to rotations in government agencies, employees could also gain valuable expertise through formal training visits with entities developing innovative technologies, such as academic research groups and start-up companies when appropriate. For example, an experiential learning program has been established as a collaborative approach to closing the knowledge gaps between emerging and innovative technologies and the premarket review of the resulting medical devices.[8]

Specialized training, such as targeted didactic courses, lectures, and modules, could also be developed based on dialogue between academic institutions and federal agencies to address the needs of interdisciplinary standing committees and "intelligence" teams. The development of this training could also be informed by participation from industry (e.g., pharmaceutical, biotechnology, and information technology sector), non-profit scientific organizations, and patient groups. In addition, training should be provided to general staff to provide at least a basic understanding of innovative technologies. More specialized training should be available to staff who are directly evaluating or managing the technologies. Curriculum could be developed in collaboration with academic and agency experts and should be regularly evaluated to determine whether revisions are needed, including whether educational tracks or specializations should be added as new technologies or areas of application emerge. In addition to technical competencies, trainings for all staff should include an exploration of regulatory and ethical considerations (e.g., transparency, risk and bias detection and management, model robustness, privacy, data protection, and accountability) related to the use of innovative technologies.

Training and education about the regulatory and ethical considerations for the use of innovative technologies should also be made available to professionals and those pursuing careers in academia, industry, or other sectors involved in the development and application of innovative technologies. For example, technology-focused sectors that are becoming increasingly involved in therapeutic development are not necessarily familiar with health-focused technologies and the associated human subject protections and regulatory implications.

In addition to formal coursework and programs, mechanisms to support information exchanges about innovative technologies with external stakeholders could include

informal forums, such as early engagement with industry (e.g., Critical Path Initiative [CPI] meetings) and virtual open houses.[4,9,10] At virtual open houses, general questions that are not specific to a particular product could be discussed. In addition, regulatory and standards setting public advisory committee meeting materials and discussions could be utilized for developing educational case studies and other training purposes.

DYNAMIC PARTNERSHIPS

As technologies continue to advance, external engagement and partnerships with end users, industry, academia, government agencies, international organizations, and other stakeholders will be critical to the development of responsive regulatory frameworks and policies. A range of diverse partnerships can help promote information sharing to inform knowledge gaps, leverage resources, and advance public health, while ensuring transparency. Although multiple engagement venues exist today in the form of professional conferences, advisory committees, and traditional public-private partnerships, innovations are being developed by an ever-increasing variety of stakeholders and more comprehensive and inclusive engagement is needed.

Targeted stakeholder engagement

Targeted engagement with a full spectrum of stakeholders, such as end users, industry, and academia, could provide regulatory agencies with valuable perspectives and insights as they evaluate innovative technologies. For example, engagement with the end users of each technology area, including patients, patient advocacy groups, physicians, and other health professionals could help agencies understand the potential risks and benefits, including how a technology may enrich an individual's experience. New centers of excellence (e.g., oncology and digital health) established by regulatory agencies are utilizing this approach, where end-user engagement could also provide valuable insight on how to build trust in new safe and effective technologies.

In addition, direct engagement with industry, including the innovators of new technologies, from pre-development to post-deployment will be needed to increase mutual learning and encourage communication about successful applications, as well as failures and lessons learned. Although regulatory agencies offer a series of formal meetings with applicants related to the development and review of medical products, informal meetings with a variety of stakeholders can be useful forums to discuss

potential scientific advances and considerations for utilizing innovative technologies in product development (e.g., CPIM, Initial Targeted Engagement for Regulatory Advice on Center for Biologics Evaluation and Research [CBER] Products[11]). These meetings allow for the exchange of ideas between regulatory experts, technology developers, and other stakeholders. These informal meetings can also help inform regulatory agencies of emerging technology developments that may impact future product development and regulations. Additionally, targeted programs to support drug development tools also provide mechanisms for early engagement and scientific collaboration with regulatory agencies to facilitate tool development and encourage innovation (e.g., Drug Development Tool [DDT] Qualification Programs[12] and Innovative Science and Technology Approaches for New Drugs (ISTAND) Pilot Program[13]). These approaches could advance innovation while preserving safety and effectiveness.

Through partnerships with academic institutions, regulatory agencies can leverage expertise in emerging or highly specialized technology areas to inform the rigorous evaluation and assessment of innovative technologies, including whether there are novel ethical and regulatory considerations that need to be addressed. In addition to academic fellowships and internships noted previously, multidisciplinary forums including experts in technology, policy, science, law, and ethics (e.g., via centers of excellence, foundations, and scientific associations) could be established to share important information, such as best practices, use cases, research, and training.

Multistakeholder collaboration and public-private partnerships

A strategy which involves multiple stakeholders across government, industry, and academia has proven to be an effective way to provide an open forum to identify and explore the potential uses of innovative technologies. Ideally, in the early stages of the development of these technologies, nimble and diverse multistakeholder collaborations should facilitate a flexible format that is non-regulatory in nature, product-independent, and allows for nonbinding advice to permit the free exchange of ideas.

Public-private partnerships (PPPs) can serve as a critical approach to advance innovative science and technology, by providing a safe harbor and pre-competitive environment for methods development and demonstration projects.[14] By involving multiple stakeholder organizations, PPPs can address issues that are beyond the capacity and resources of a single organization. They usually include at least one nonprofit or 501(c)(3) organization that acts as a convener, with partners across

TABLE 1 Examples of public-private partnerships evaluating novel methods and technologies

Practical approaches for embedding trials into health care settings[15]	Biomarkers consortium[16]	Rare disease cures accelerator-data and analytics platform[17]	COVID-19 evidence accelerator[18]	Collaborative cloud-based computing[19]
Organization: Clinical Trials Transformation Initiative (CTTI)	**Organization:** Foundation for National Institutes of Health (FNIH)	**Organization:** C-Path Institute, in cooperation with the National Organization for Rare Disorders (NORD)	**Organization:** Reagan-Udall Foundation (RUF) and Friends of Cancer Research (Friends)	**Organization:** Accumulus Synergy Inc.
Purpose: To determine the feasibility of incorporating interventional trials into clinical care settings and the associated benefits and risks, including barriers and potential solutions	**Purpose:** To accelerate the discovery, development, approval, and utilization of biomarkers in drug development and in broader applications of disease prevention, detection, and treatment	**Purpose:** To accelerate drug development for rare diseases, utilizing a rare disease information database and analytics platform to help understand how rare diseases progress and outcome measures for potential new drugs	**Purpose:** To accelerate the understanding of and response to COVID-19 by leveraging RWD from across the country, utilizing a collaborative venue for sharing expertise and data across different work streams. The accelerator also explores other models of rapid evidence generation that could inform the effort to address current and future public health emergencies.	**Purpose:** To improve data management and information exchange between pharmaceutical sponsors, FDA, and potentially other global health authorities using advanced technologies, such as an artificial intelligence enabled, cloud-based platform
Key elements or deliverables: • To provide best practice recommendations and developing a collection of case studies with operational approaches	**Key elements or deliverables:** • To provide tools that support decision making during a drug development trial • I-SPY2 trial providing improved clinical trials and biomarker use for breast cancer • Kidney Safety project obtained FDA Qualification for a composite biomarker	**Key elements or deliverables:** • To provide a resource where researchers and drug developers can access data about rare diseases and how they progress, leading to new insights about the diseases • To provide a mechanism to develop new tools and methodologies to improve clinical trial design	**Key elements or deliverables:** • To develop common data elements for data collection in a more uniform approach, allowing for rapid aggregation and analysis of RWD for COVID-19 • To rapidly identify patient characteristics and treatment patterns	**Key elements or deliverables:** • To develop a cloud-based platform that will offer secure workspaces and workflows, streamline processes by leveraging advanced technology, and allow for enhanced collaboration, and coordination between health authorities and sponsors

Abbreviations: COVID-19, coronavirus disease 2019; FDA, US Food and Drug Administration; RWD, real-world data.

government, industry, academic, and other organizations. These partnerships are currently being utilized in areas ranging from rare diseases to coronavirus disease 2019 (see Table 1).

PPPs are increasingly using adaptive models, such as accelerators (investment of resources to accelerate growth in a specific area) and sandboxes (supervised opportunities to test innovations) to address needs, share ideas, and provide a neutral space to experiment with new technologies. These more dynamic PPP models should be leveraged to quickly respond to innovative technologies and public health needs, while rapidly evolving or expanding to address new areas and sunsetting, as appropriate.

Interagency collaborations

Interagency partnerships can also provide a valuable mechanism for exchanges among policy, regulatory, scientific, and research groups. Currently, these partnerships are generally established between agencies with similar missions and focus. In considering areas of converging technologies, it will be essential to expand these partnerships to include a broader diversity of agencies focused on public health, national security, regulatory and standards development, and cutting across multidisciplinary basic and applied research. Joint workshops, collaborative projects, and exchanges of personnel can serve as mechanisms to leverage complementary expertise and address regulatory science challenges in areas of rapidly developing technologies.

International collaborations

As the development and use of innovative technologies become increasingly global, collaborations with the international community, including foreign regulatory agencies and international organizations, should continue to be prioritized. Bilateral and multilateral collaborations will provide regulatory agencies with a better understanding of how innovative technologies are being used globally and whether there are novel issues that need to be addressed. They also provide an opportunity to engage in dialogue with a variety of international experts to gain perspectives and expertise on new technologies and to explore potential regulatory approaches for their safe, ethical, and responsible use. For example, participation in international forums, particularly in international standards bodies, such as the International Convention for Harmonization of the Technical Requirements for Pharmaceuticals

for Human Use (ICH) and the International Medical Device Regulators Forum (IMDRF), can be used to encourage dialogue regarding developing and harmonizing standards for the incorporation of promising new technologies in drug development. Important platforms, such as the ICH and IMDRF, may also benefit from exploring more frequent and targeted engagements beyond their traditional membership to enhance mutual learning and to further enrich deliberations. Coordination and information exchange forums, such as the International Coalition of Medicines Regulatory Authorities (ICMRA), can also serve to help identify

TABLE 2 Considerations for a responsive and agile regulatory ecosystem

Adaptive regulatory framework
- Internal multidisciplinary "intelligence" teams focused on innovative technologies
- A responsive, risk-based, and iterative policy development process, with mechanisms for post-deployment evaluation and frequent updating, if necessary
- Stable principles that are widely applicable combined with agile policy making and regulation development
- Mechanisms for effective communication with a wide range of stakeholders to discuss current applications of evolving technologies

Effective workforce development
- A comprehensive talent acquisition strategy that meets requirements for career positions and short-term expertise
- Internal capacity building to help fill gaps in expertise
- Specialized training for internal interdisciplinary standing committees and "intelligence" teams
- Training for general staff to provide an understanding of innovative technologies
- General education programs to promote understanding of the regulatory and ethical considerations for the use of innovative technologies

Dynamic and diverse partnerships
- Engagement with end users of new technologies to better understand the potential risks and benefits and gain insight on how to build trust in the technology
- Engagement with emerging technology sectors to increase transparency and encourage bilateral communication
- Partnerships with academic institutions to leverage expertise in emerging or highly specialized technology areas
- Multi-stakeholder collaborations (e.g., PPPs) to provide an open forum to advance the potential uses of emerging technologies
- Interagency collaborations to provide a valuable mechanism for scientific exchange between policy, regulatory, scientific, and research groups
- International collaborations to gain a better understanding of how innovative technologies are being used globally and whether there are potential novel issues that need to be addressed

Abbreviation: PPPs, public-private partnerships.

areas where collaborations between regulatory bodies is most needed to help ensure responsiveness to innovations globally.

CONCLUSION

The convergence of rapid advances in areas such as computing power, data analysis, AI, and digital health tools must be matched with robust and well-informed regulatory approaches. To maximize the benefits of these innovations, establishing a stable and nimble regulatory ecosystem that can facilitate innovation while safeguarding the public is a necessity. Creating an adaptive policy-making infrastructure that is suited to address evolving complexities, developing a workforce equipped with the needed expertise, and forming more diverse and effective collaborations with a broader group of stakeholders are all important steps that should be advanced simultaneously to reach this goal (see Table 2). Consistent interdependent efforts to capitalize on the strength of existing collaborations and experiences, while at the same time shaping the future of responsive regulations will also be needed.

These key steps and models provide a roadmap for future progress toward a regulatory ecosystem that is responsive to rapidly developing innovations. Whereas recruiting and retaining candidates with needed expertise, training existing staff, and increasing awareness of innovations pose challenges to advance some of these approaches, implementing comprehensive and sustained initiatives focused on expanding and diversifying staff expertise, using targeted recruiting and training strategies, and developing a range of collaborations can help address these challenges and advance an agile regulatory ecosystem. In considering the effort and resource needs, it is also important to weigh the opportunity cost of not preparing for and responding adequately to innovations that can be disruptive to current medical product development. The considerations outlined in this paper can be further refined and updated as we continue to collectively learn and adapt to the challenges and opportunities posed by converging technologies.

CONFLICT OF INTEREST

A.L. reports grants from Santen, personal fees from Genentech, personal fees from US FDA, grants from Carl Zeiss Meditec, Inc., personal fees from Topcon, personal fees from Gyroscope, non-financial support from Microsoft, grants from Regeneron, outside the submitted work. All the other authors declare no competing interests.

DISCLAIMER

The opinions expressed in this manuscript are those of the authors and should not be interpreted as the position of the US Food and Drug Administration.

REFERENCES

1. Vamathevan J, Clark D, Czodrowski P, et al. Applications of machine learning in drug discovery and development. *Nat Rev Drug Discov.* 2019;18(6):463-477.
2. Schneider P, Walters WP, Plowright AT, et al. Rethinking drug design in the artificial intelligence era. *Nat Rev Drug Discov.* 2020;19(5):353-364.
3. Weissler EH, Naumann T, Andersson T, et al. The role of machine learning in clinical research: transforming the future of evidence generation. *Trials.* 2021;22(1):537.
4. U.S. Food and Drug Administration. *Framework for FDA's Real World Evidence Program*, 2018.
5. Partership for Public Service. *Mobilizing Tech Talent: Hiring Technologists to Power Better Government*, 2018.
6. World Economic Forum. *Agile Governance: Reimagining Policy-making in the Fourth Industrial Revolution*, 2017.
7. 18 U.S.C. § 202(a), 2010.
8. U.S. Food and Drug Administration. *Center for Devices and Radiological Health, Experiential Learning Program*. Accessed February 11, 2022. https://www.fda.gov/science-research/fda-science-jobs-and-scientific-professional-development/cdrhs-experiential-learning-program
9. U.S. Food and Drug Administration. *Center for Drug Evaluation and Research. Critical Path Innovation Meetings*, 2015.
10. U.S. Food and Drug Administration. *Critical Path Innovation Meetings (CPIM)*. Accessed February 11, 2022. https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/critical-path-innovation-meetings-cpim
11. U.S. Food and Drug Administration. *Initial Targeted Engagement for Regulatory Advice on CBER Products*. Accessed February 8, 2022. https://www.fda.gov/vaccines-blood-biologics/industry-biologics/interact-meetings
12. U.S. Food and Drug Administration. *Drug Development Tool (DDT) Qualification Programs*. Accessed February 10, 2022. https://www.fda.gov/drugs/development-approval-process-drugs/drug-development-tool-ddt-qualification-programs
13. U.S. Food and Drug Administration. *Innovative Science and Technology Approaches for New Drugs (ISTAND) Pilot Program*. Accessed February 10, 2022. https://www.fda.gov/drugs/drug-development-tool-ddt-qualification-programs/innovative-science-and-technology-approaches-new-drugs-istand-pilot-program
14. Bahinski AFM, McLellan M, Psaty B, Roden D, Steele S. *Scientific Engagement at FDA: A Report to the FDA Science Board from the Scientific Engagement Subcommittee*. United States Food and Drug Administration Science Board; 2016.
15. Clinical Trials Transformation Initiative. *Trials in Health Care Settings*. Accessed February 11, 2022. https://ctti-clinicaltrials.org/our-work/novel-clinical-trial-designs/integrating-clinical-care/
16. Foundation for the National Institutes of Health. *Biomarker Consortium*. Accessed February 11, 2022. https://fnih.org/what-we-do/biomarkers-consortium

17. Critical Path Insitute. *Rare Disease Cures Accelerator-Data and Analytics Platform*. Accessed February 11, 2022. https://c-path.org/programs/rdca-dap/

18. Friends of Cancer Research. *COVID-19 Evidence Accelerator*. Accessed February 11, 2022. https://friendsofcancerresearch.org/covid19?eType=EmailBlastContent&eId=dcda698b-85d5-47f4-b0e0-beb131c76024

19. Accumulus Synergy Inc. *Collaborative Cloud-Based Computing*. Accessed February 11, 2022. https://www.accumulus.org/