JPPT | Invited Commentary

The Precompetitive Space for Drug or Vaccine Development: What Does It Look Like Now and What Could It Look Like in the Future?

Jeffrey S. Barrett, PhD

ABBREVIATIONS COVID-19, Coronavirus disease 19; C-Path, Critical Path Institute; DDT, drug development tool; FDA, US Food and Drug Administration; ICODA, International COVID-19 Data Alliance; IOM, Institute of Medicine; NGO, nongovernmental organization; R&D, Research and Development

KEYWORDS collaboration; drug and vaccine development; neutral convener; precompetitive space

J Pediatr Pharmacol Ther 2023;28(5):465–472

DOI: 10.5863/1551-6776-28.5.465

Competition – How, Why, etc.

The pharmaceutical industry including small and large organizations and biotech as well as other stakeholders in the health arena are increasingly aware of the benefits of working together in the precompetitive phase to address common problems. While they rightly remain focused on developing their own independent products and services in healthy competition, there is an increased awareness of the need to improve precompetitive efficiency by identifying and addressing common issues. A major challenge is defining the domain of precompetitive research. The basic biology, the understanding of disease, biomarkers of prognosis, and even drug responses all can be areas of precompetitive research and development (R&D).

Precompetitive collaboration allows a group of competing companies to come together to develop a solution for a problem that they all share, and from which none of them would gain a competitive advantage. Although the primary goal is often cited as the development of that solution, the process of conversing and collaborating is in itself of great value, and a project that enables colleagues from across the industry to develop closer working relationships with each other can be beneficial, even if the deliverables do not live up to expectations.

Several different precompetitive collaboration types have evolved to date. Collaborations are typically classified regarding whether they have open or restricted participation and open or restricted outputs. They also vary according to their goals. Likewise, there are typically 2 broad collaboration goals: to build enabling platforms and to conduct research. These goals can be further subdivided by the 4 different types of outputs they produce, including the development of standards and tools, the generation and aggregation of data, knowledge creation, and product development.

In general, collaborations aimed at building enabling platforms focus on developing standards and tools or generating and aggregating data to achieve a necessary scale for research. Collaborations that conduct research seek to create new knowledge or to turn that knowledge into a product by accessing resources and capabilities across organizations. Barriers to sharing data are often an obstacle. Different data systems, privacy rules, and sharing protocols often make it difficult for community-based organizations in nonmedical sectors to work in concert with health care organizations.

Regulatory hurdles, complex research for new drug and vaccine targets, and the low predictability of animal models are some examples of why both drug and vaccine industries are struggling. Such internal and external challenges make it necessary for companies to improve their R&D efficiencies by methods including outsourcing to reduce overhead costs, installation of proof-of-concept organizations, or by enhanced scientific rigor in data-driven project decision-making.[1] The recent pandemic also provided a heightened sense of urgency to accelerating collaborations beyond R&D, including manufacturing competitors' products,[2] conducting platform trials,[3] and sharing precompetitive data without the usual contractual and legal bottlenecks.[4,5] One of the more publicly acknowledged short-term, precompetitive collaborations during the pandemic was the ICODA (International COVID-19 Data Alliance) initiative,[6] an open and inclusive global collaboration of leading life science, philanthropic, and research organizations that came together to harness the power of health data to respond to the COVID-19 pandemic.

Some pioneering organizations started to complement their internal R&D efforts through collaborations as early as the 1990s. In recent years, various extrinsic and intrinsic factors created an opportunity for external sources of innovation resulting in new models for open

innovation, such as open sourcing, crowdsourcing, public-private partnerships, innovations centers, and the virtualization of R&D. This new reality also influences the construction and intention around precompetitive collaboration. This perspective challenges the preconceptions of the precompetitive space from the standpoint of their value, construction, and sustainability and highlights the necessity of a convener to facilitate the scope and intentions of precompetitive collaborations particularly as they evolve over time.

Precompetitive for Whom?

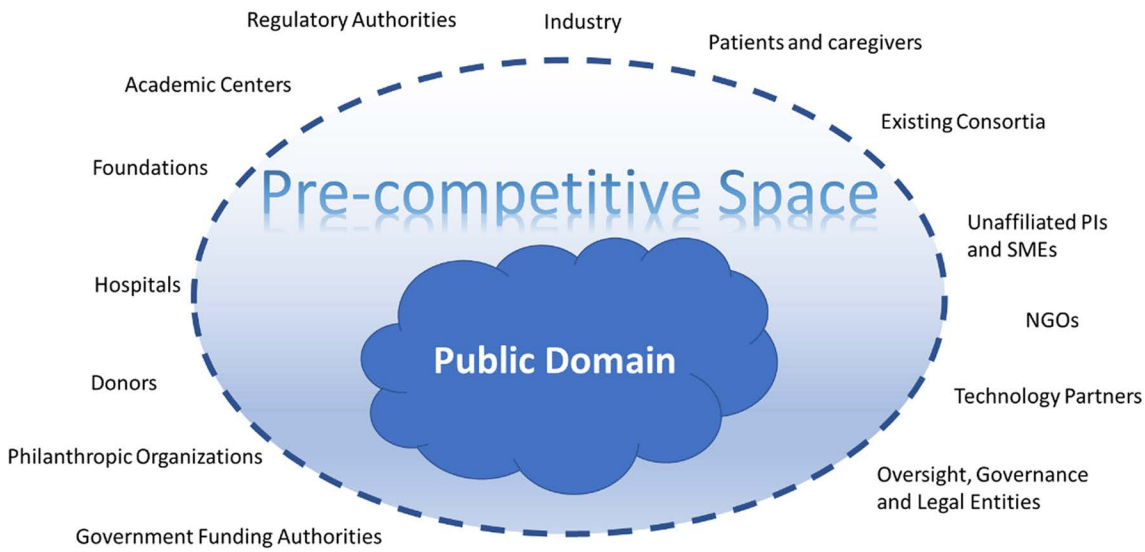
Precompetitive collaboration is often generalized as 2 or more companies within the same industry, coming together to address a shared problem or pain point that does not affect direct business competition and is often focused on joint social or environmental impacts. These private sector partners might also be joined by community actors such as nongovernmental organizations (NGOs), donors, or foundations in the target region or value chain. Together, they forge new solutions to overcome shared obstacles—unlocking opportunities for the partners, and the ecosystem they all share. See the Figure for a conceptualized view of the precompetitive space and the stakeholders that often comprise the relevant ecosystem. Keep in mind that many of the stakeholders contribute to the precompetitive space in a variety of ways and that the contributions are about more than data. Precompetitive collaboration empowers the private sector to meaningfully address systemic challenges by coordinating sustainability efforts; bringing a wider range of perspectives, resources, and expertise to the table; and scaling more impactful solutions.

The notion of precompetitive collaboration is viewed as a positive approach in general allowing a group of competing companies to come together to develop a solution for a problem that they all share, and from which none of them would gain a competitive advantage. Although the primary goal is often cited as the development of that solution, the process of conversing and collaborating is of great value, and a project that enables colleagues from across the industry to develop closer working relationships with each other can be beneficial, even if the deliverables do not live up to expectations. Simply waiting for an existing group to come up with something might appear to be risk-free, and certainly reduces effort, but passive bystanders to precompetitive collaboration projects are typically losing out on more than they imagine.

The Role of the Convener and Credibility as a "Neutral" Convener

Success in a precompetitive collaboration is often reliant on a convener to develop a successful data ecosystem for the data collaboration. There are various roles essential to the inner working of a data ecosystem that enables precompetitive collaboration. Typically, there are the following main roles: data suppliers, data intermediaries, and data consumers.[7] This view holds true also for data collaboratives, as the minimal value chain therein is also about matching data supply and data demand.[8] The term *convener* typically refers to a neutral third party (i.e., facilitator or mediator) who gathers information to test the feasibility of a particular stakeholder involvement process or outcome. Neutral in this context refers to impartiality and a lack of bias in decision-making.

Figure. Precompetitive emphasis and stakeholders. *NGOs, non-governmental organizations; PIs, Principle Investigators; SMEs, Subject Matter Experts*.



Two commonly viewed neutral conveners are the Institute of Medicine (IOM) and the Critical Path Institute (C-Path). The IOM has a singular capacity to bring together various stakeholders to work together on health problems of shared interest. Through both ongoing roundtables, sometimes called forums, and through unique partnerships, the IOM shapes the conversation around health and health care. Partnerships with outside organizations bring complementary strengths and enable the IOM to amplify the size and character of its audience and the impact of its work.[11] The IOM has pursued a number of such new opportunities with outside organizations in recent years. C-Path is a nonprofit, public-private partnership with the US Food and Drug Administration (FDA), created under the auspices of the FDA's Critical Path Initiative program in 2005. C-Path's aim is to accelerate the pace and reduce the costs of medical product development through the creation of new data standards, measurement standards, and methods standards that aid in the scientific evaluation of the efficacy and safety of new therapies. These precompetitive standards and approaches have been termed *drug development tools* (DDTs) by the FDA, which established a process for official review and confirmation of their validity for a given context of use. C-Path orchestrates the development of DDTs through an innovative, collaborative approach to the sharing of data and expertise. C-Path strives to build consensus among participating scientists from industry and academia with FDA participation and iterative feedback. The process culminates in a formal application to FDA for official "qualification" of the DDT for a given use in product development.

Table 1 provides a more extensive list of generally regarded neutral conveners including several from sectors outside of life sciences along with "case for" and "case against" neutrality considerations. In most situations the "case for" sentiments are well appreciated by their stakeholders, while the "case against" assessment reflects the view from some that these organizations have a limited geographic or disciplinary scope and not as broad in their convening scope as necessary nor as they could be. The global perspective is certainly not a requirement for a neutral convener but it does occasionally project an optics concern for restriction to a more colonial interest.

Specific Examples. There are in fact some good examples of organizations working in the precompetitive space in certain therapeutic areas (e.g., Oncology[12]) and for certain purposes (e.g., genomics[13] and data standards (e.g., Pistoia Alliance) that transcend multiple and diverse stakeholders. Table 2 provides a list of precompetitive collaborations that represent a multistakeholder environment with high visibility and demonstrated impact.

Working Relationships

Pharma companies have increasingly moved away from internal R&D constructs towards more open and collaborative R&D models following a paradigm of open innovation.[23] In this approach, they establish specific collaborations with academic centers of excellence, build innovation centers, create joint ventures with academic institutions (public-private partnerships), establish precompetitive consortia, or experiment with crowdsourcing and virtual R&D.[24–27] Some models even let competitors collaborate and become partners,[28] though these are more rare. Currently, many companies have put greater emphasis on leveraging external knowledge, licensing or acquiring drug candidates, and changing their R&D models from primarily inside-driven concepts to plans that more closely follow the open innovation paradigm.

Bloom et al[29] evaluated the elements necessary for successful collaboration between patient groups and academic and industry sponsors of clinical trials, in order to develop recommendations for best practices for effective patient group engagement. The most important elements for effective patient group engagement include establishing meaningful partnerships, demonstrating mutual benefits, and collaborating as partners from the planning stage forward. Although there is a growing appreciation by sponsors about the benefits of patient group engagement, there remains some resistance and some uncertainty about how best to engage. Barriers included mismatched expectations and a perception that patient groups lack scientific sophistication and that "wishful thinking" may cloud their recommendations. The larger question here is how do you know you got it right and are on a good path for the future. What are good metrics for successful precompetitive collaboration? What does a healthy precompetitive collaboration look like?

Each stakeholder likely has their own perspective on this topic. Industry's perceptions of the domain of precompetitive research have been expanding, though internal tensions can point to areas of ambiguity and the boundary can vary among companies and academic researchers. Universities and other organizations need to take advantage of multiple opportunities to change traditional practices. New ways of measuring achievement would provide incentives for more researchers to participate in precompetitive collaborations. What is clear from the examples discussed herein is that elements of successful collaborations should include the necessity of a good convener, plans for sustainability, responsible and constructive social behaviors, and customized platforms that can evolve with the demands of the collaboration. A key observation in the C-Path example has been the benefit of creating a dynamic research community with clear goals, a research agenda that evolves with the science, and a modern data and compute environment that encourages collaboration.[30,31] When certain facilitating factors are present, intended collaborators can overcome competitive market

Table 1. Institutions Often Viewed as Neutral Conveners

Institution	Origin/Focus	Case for	Case Against
National Institutes of Health (NIH) https://www.nih.gov/about-nih/what-we-do/nih-almanac/about-nih	Seek and fund research about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability	Broad range of multiple stakeholders around the world	The steward of medical and behavioral research for the United States and likewise US centric
Children's Oncology Group (COG) https://childrensoncologygroup.org/childrens-oncology-group	Widely recognized as a premier collaborative research organization, having enrolled more children with cancer in clinical trials than any other organization in the world	NCI-supported member group of the National Clinical Trials Network. Over 10,000 members; brings together physicians, scientists, nurses, psychologists, and others working to beat cancer in children, adolescents, and young adults at >200 leading children's hospitals, universities, and cancer centers across North America, Australia, and New Zealand	Still often viewed as US centric with data collected from COG trials not easily shared despite messaging[9]
Critical Path Institute (C-Path) https://c-path.org/	Forges global partnerships and collaborations that include the FDA, EMA, and Japan's PMDA and private industry	FDA's intention in creating was as a global, independent, nonprofit organization dedicated to the generation of actionable solutions to transform the medical product development	Still often viewed as US centric based on contributed data sources and funding[10]
Institute of Medicine (IOM), now National Academy of Medicine https://nam.edu/	Independent, nonprofit organization that works outside of government to provide unbiased and authoritative advice to decision-makers and the public	Credible in convening stakeholders at national, state, and local levels to lay the groundwork for action providing resources and technical assistance; building multisector public-private partnerships; and encouraging organizations and policymakers to take leadership roles in advancing health equity	Viewed as US centric given stated goals and emphasis

(Table cont. on page 469)

dynamics and competing institutional priorities to align financial incentives, quality measurement, and data feedback to support practice transformation. Lessons from multistakeholder initiatives may be helpful to promote more and better collaborations (precompetitive or not) in the future. While regulatory authorities have suggested that precompetitive research offers the highly competitive pharmaceutical and medical device industries a way to reduce ballooning development costs,[32] it will be up to sponsors to develop and sustain

Table 1. Institutions Often Viewed as Neutral Conveners *(cont.)*

Pistoia Alliance https://www.pistoiaalliance.org/	NGO with over 200 member companies across the life science ecosystem collaborating across more than 25 projects and communities to advance science. Our members include 18 of the top 20 global pharma companies by revenue, patient-led research groups, technology and solution providers, academic institutions, publishers, and commercial research groups	Focus on identifying root causes of inefficiencies, working with regulators to adopt new standards or helping researchers implement AI effectively. Currently >100 member companies—ranging from global organizations, to medium enterprises, to start-ups, to individuals—collaborating on projects that generate value for the worldwide life sciences community	Foundation by industry members creates emphasis in industrial and academic/NGO landscape as opposed to other sectors (e.g., hospital, regulatory)
AI Innovation of Sweden https://www.ai.se/en/news/ai-innovation-sweden-officially-launched-0	40 stakeholders will use cooperation and colocation to accelerate innovation and research in practical applied AI	Main funding has come from Sweden's innovation agency, Vinnova	Foundation by industry members creates emphasis in industrial and regulatory landscape; entirely centric to Sweden
AMdEX, Amsterdam Data Exchange https://amdex.eu/	AMdEX is developing a digital notary. Offering legal contracts to organizations that want to share data. Even the most sensitive data. AMdEX translates data-sharing agreements into machine-readable policies that can automatically be enforced	Data exchanges are key to democratization, fair market competition, and efficiency—thought leaders on the topic of fair rule for data commons	European regional centric, often Amsterdam centric by design and intention

AI, artificial intelligence; AMdEX, Amsterdam Data Exchange; COG, Children's Oncology Group; EMA, European Medicines Agency; FDA, US Food and Drug Administration; NCI, National Cancer Institute; NGO, non-governmental organizations; PMDA, Pharmaceuticals and Medical Devices Agency

these efforts in conjunction with a diverse stakeholder community so that all benefit in some way.

Article Information

Affiliations. Bioinformatics (JSB), Aridhia Digital Research Environment, Glasgow, Scotland.

Correspondence. Jeffrey S. Barrett, PhD, FCP; Jeff.barrett@aridhia.com

Disclosure. The author declares no conflicts or financial interest in any product or service mentioned in the manuscript, including grants, equipment, medications, employment, gifts, and honoraria. The author attests to meeting the four criteria recommended by the ICMJE for authorship of this manuscript.

Ethical Approval and Informed Consent. Not applicable.

Acknowledgments. Thanks to David Sibbal for his thoughtful review of the paper. Data availability statement: Data generated herein are based on literature and web review but are available from the PI, Jeffrey S. Barrett, PhD, FCP, upon request.

Submitted. May 11, 2023

Accepted. May 14, 2023

Table 2. Recent Examples of Precompetitive Collaborations

Collaboration	Stakeholders	Purpose	Impact
Data standards including projects on: • Natural language processing • Ontologies • Semantic enrichment • Others	Pistoia Alliance leads industry (100 member companies) and NGO/academic (>50) stakeholders	Seeks to lower barriers to R&D innovation by providing a legal framework to enable clear and secure precompetitive collaboration	Identified root causes that led to R&D inefficiencies; developing best practices and technology pilots to overcome common obstacles
Therapeutic area emphasis:			
Oncology[14]	Many with great diversity based on emphasis (e.g., bioinformatics resources and standards, biomarker consortium, I-SPY 2 trial, pediatrics, specific cancers)	• More efficient drug candidate identification and selection while minimizing patient exposure to drugs with low PTOS	• Shared biomarker data; consensus on data standards • Successful completion of platform trials
Parkinson Disease[15]	C-Path, MJFF and other Parkinson disease foundations, FDA, industry partners and academic collaborators	• Regulatory-approved endpoints, trial designs, and modeling tools • Identification of indicators of early disease state markers • Development of reliable biomarkers to monitor disease progression • Understanding disease subtypes, enable patient stratification for more efficient clinical trials	• Regulatory-approved DPMs and CTS tools • Shared biomarker data • Collaborative clinical trials
Rare Diseases[16,17]	Global academic, regulatory, and industrial partners and including patients, patient advocates, NGOs, and foundations	• Pool resources and knowledge including team science, research networks, novel funding models, shared knowledge platforms, and innovative regulatory frameworks	• Data-sharing platforms, clinical trial collaboration, collaboration on biomarker, endpoint, and patient selection.
Genomics:			
The UK Biobank Exome Sequencing Consortium (UKB-ESC)[18]	Private-public partnership between the UKB and eight biopharmaceutical companies	Complete the sequencing of exomes for all ~500,000 UKB participants	Exome data from 200,643 UKB enrollees available. Data include ~10 million exonic variants—resource of rare coding variation valuable for drug discovery
HBO Obesity Project *The Weight of the Nation* documentary[19,20]	NIH, NICHD, CDC, IOM, academic investigators, and HBO	To understand, treat, and prevent obesity, including the work of NIH and NICHD researchers. The program is part of a larger initiative to raise awareness about obesity and its health risks nationwide	Perceived to play a role in influencing beliefs, intentions, and policy support regarding obesity prevention

Table 2. Recent Examples of Precompetitive Collaborations *(cont.)*

Food Forum part of Forum for the Future[21]	Leading international sustainability nonprofit running out of offices in the United Kingdom, United States, India, and Singapore; partnership with business, governments, and civil society to accelerate the shift towards a just and regenerative future	Develop a sustainable future for food	• Supply chain synergies • Secured capital markets investment • Bioenergy assessment
Forum on Drug Discovery, Development, and Translation[22]	Stakeholders include government, academia, industry—including pharmaceutical, biotechnology, and digital health companies, foundations, and disease and patient advocacy	Provides a neutral platform for stakeholders to highlight critical issues, spur cross-sector collaboration, and inspire action	Held and published numerous workshops on innovative topics including virtual clinical trials, RWD/RWE, diagnostics to detect antibiotic resistance, etc.

CDC, Centers for Disease Control and Prevention; C-Path, Critical Path Institute; CTS, Clinical Trial Simulations; DPMs, Disease Progression Models; FDA, US Food and Drug Administration; HBO, Home Box Office; IOM, Institute of Medicine; MJFF, Michael J Foxx Foundation; NGO, non-governmental organizations; NICHD, Eunice Kennedy Shriver National Institute of Child Health and Human Development; NIH, National Institutes of Health; PTOS, Probability of Technical Success; R&D, research and development; RWD/RWE, Real-world data/real world evidence; UKB-ESC, UK Biobank-Exome Sequencing Consortium

References

1. Schuhmacher A, Gassmann O, McCracken N, et al. Open innovation and external sources of innovation: an opportunity to fuel the R&D pipeline and enhance decision making. *J Transl Med*. 2018;16:119.
2. Bown CP, Bollyky TJ. How COVID-19 vaccine supply chains emerged in the midst of a pandemic. *World Econ*. 2022;45(2):468–522.
3. Vanderbeek AM, Bliss JM, Yin Z, Yap C. Implementation of platform trials in the COVID-19 pandemic: a rapid review. *Contemp Clin Trials*. 2022;112:106625.
4. Moorthy V, Henao Restrepo AM, Preziosi MP, Swaminathan S. Data sharing for novel coronavirus (COVID-19). *Bull World Health Organ*. 2020;98(3):150.
5. Delacroix S, Lawrence ND. Bottom-up data Trusts: disturbing the "one size fits all" approach to data governance. *International Data Privacy Law*. 2019; 9(4). Accessed May 6, 2023. https://academic.oup.com/idpl/article/9/4/236/5579842
6. Dron L, Kalatharan V, Gupta A, et al. Data capture and sharing in the COVID-19 pandemic: a cause for concern. *Lancet Digit Health*. 20224(10):e748–e756.
7. Susha I, van den Broek T, van Veenstra A-F, Linåker J. An ecosystem perspective on developing data collaboratives for addressing societal issues: the role of conveners. *Government Information Quarterly*. 2023;40(1):101763.
8. Susha I, Janssen M, Verhulst S. Data collaboratives as a new frontier of cross-sector partnerships in the age of open data: taxonomy development. In: *Proceedings of the 50th Hawaii International Conference on System Sciences*, Waikoloa, HI, 2017:2691–2700.
9. Plana A, Furner B, Palese M, et al. Pediatric Cancer Data Commons: federating and democratizing data for childhood cancer research. *JCO Clin Cancer Inform*. 2021;5:1034–1043.
10. CPATH Annual Report. 2022. Accessed May 15, 2023. https://c-path.org/wp-content/uploads/2022/12/Annual-Report-2022.pdf
11. Fallon HJ. The Institute of Medicine and its quality of healthcare in America reports [discussion in *Trans Am Clin Climatol Assoc*. 2002; 113:125]. *Trans Am Clin Climatol Assoc*. 2002;113:119–124.
12. Institute of Medicine. Types of precompetitive collaborations. In: *Extending the Spectrum of Precompetitive Collaboration in Oncology Research: Workshop Summary*. Washington, DC: National Academies Press; 2010. Accessed May 15, 2023. https://www.ncbi.nlm.nih.gov/books/NBK210028/
13. Institute of Medicine. Roundtable on Translating Genomic-Based Research for Health: 3. Requisites for successful precompetitive collaboration. In: *Establishing Precompetitive Collaborations to Stimulate Genomics-Driven Product Development: Workshop Summary*. Washington, DC: National Academies Press; 2011. Accessed May 15, 2023. https://www.ncbi.nlm.nih.gov/books/NBK54320/
14. Balogh E, Nass SJ, Patlak, M, eds. *Extending the Spectrum of Precompetitive Collaboration in Oncology Research: Workshop Summary*. Washington, DC: National Academies Press; 2010. Accessed May 15, 2023. https://www.ncbi.nlm.nih.gov/books/NBK210036/pdf/Bookshelf_NBK210036.pdf
15. Stephenson D, Hu MT, Romero K, et al. Precompetitive Data sharing as a catalyst to address unmet needs in Parkinson's disease. *J Parkinsons Dis*. 2015;5(3):581–594.
16. Julkowska D, Austin CP, Cutillo CM, et al. The importance of international collaboration for rare diseases research: a European perspective. *Gene Ther*. 2017;24(9):562–571.
17. Boycott KM, Lau LP, Cutillo CM, Austin CP. International collaborative actions and transparency to understand,

diagnose, and develop therapies for rare diseases. *EMBO Mol Med*. 2019;11(5):e10486.
18. Szustakowski JD, Balasubramanian S, Kvikstad E, et al. Advancing human genetics research and drug discovery through exome sequencing of the UK Biobank. *Nat Genet*. 2021;53:942–948.
19. NIH press release. NIH research featured in HBO documentary series on obesity. 2012. Accessed Month, day, year. https://www.nih.gov/news-events/news-releases/nih-research-featured-hbo-documentary-series-obesity
20. Luecking CT, Noar SM, Dooley RM, et al. Impact of Weight of the Nation community screenings on obesity-related beliefs. *Am J Prev Med*. 2017;52(3 suppl 3):S315–S321.
21. Forum for the Future. 2020. Accessed Month day, year. https://www.forumforthefuture.org/blog/building-the-future-of-food-during-crisis
22. National Academies of Sciences, Engineering, and Medicine. Forum on Drug Discovery, Development, and Translation: 2022 Annual Review. Washington, DC: The National Academies Press; 2023. Accessed Month day, year. https://doi.org/10.17226/26954
23. Chesbrough H. *Open Innovation: The New Imperative From Creating and Profiting From Technology*. Brighton: Harvard Business School Press; 2003.
24. Schuhmacher A, Germann PG, Trill H, Gassmann O. Models of open innovation in the pharmaceutical industry. *Drug Discov Today*. 2013;18:1133–1137.
25. Howe J. *Crowdsourcing: Why the Power of the Crowd Is Driving the Future of Business*. New York: Crown Business Publishing; 2008.
26. Gassmann O, von Zedtwitz M. Trends and determinants of managing virtual R&D teams. *R&D Manag*. 2003;33(3):243–262.
27. Mittleman B, Neil G, Cutcher-Gershenfeld. Precompetitive consortia in biomedicine—how are we doing? *Nat Biotechnol*. 2013;31:979–985.
28. Holmes D. A new chapter of innovation. *Nature*. 2016; 533:S54–S55.
29. Bloom D, Beetsch J, Harker M, et al. The rules of engagement: CTTI recommendations for successful collaborations between sponsors and patient groups around clinical trials. *Ther Innov Regul Sci*. 2018;52(2):206–213.
30. Larkindale J, Betourne A, Borens A, et al. Innovations in therapy development for rare diseases through the Rare Disease Cures Accelerator-Data and Analytics Platform. *Ther Innov Regul Sci.* 2022 Sep;56(5):768-776.
31. Barrett JS, Betourne A, Walls RL, et al. The future of rare disease drug development: the rare disease cures accelerator data analytics platform (RDCA-DAP). *J Pharmacokinet Pharmacodyn* published online May 2, 2023.
32. Woodcock J. Precompetitive research: a new prescription for drug development? *Clin. Pharmacol Ther*. 2010;87(5):521 –523.