POLICY

Rx for Innovation: A path forward for us all

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The role played by the United States in biomedical research and innovation did not happen by chance. And it most certainly is not guaranteed to continue indefinitely. This leadership position arose from decades of commitment to federal funding and pro-innovation policies, plus ingenuity and entrepreneurship. Now, a new entrepreneur looms large—the health citizen—and we believe biomedical research and development (R&D) efficiency and effectiveness will be improved if all stakeholders embrace health citizenship (https://twitter.com/hashtag/healthcitizenship?src=hash).

What do we mean by health citizenship? Everyone is, or will be, a patient. This new health citizenship movement can provide the platform for citizens—healthy and ill—to engage with researchers, industry, and regulators. Consider this as a parallel to political citizenship, for which we have rights and responsibilities, and in our democracy, we strive for both participation and representation. We see health citizenship as a two-way street: (i) Individual citizens have a responsibility to engage in their own heath and in the biomedical research system, and (ii) "the system" has a responsibility to facilitate and value participant engagement.

This concept came from a series of *FasterCures* interviews with more than 150 thought leaders across eight sectors of biomedical research for our Rx for Innovation project. From those insights, we created a series of recommendations for the new administration (and, for that matter, all of us) to drive toward (www.fastercures.org/innovation). From this project and our work across the R&D system, we have identified at least three topics in which health citizenship can have an immediate and lasting impact.

CLINICAL TRIALS

The time is now to revolutionize clinical trials—including design, recruitment, and retention—and the U.S. government can contribute both by enabling new technologies through funding, policies, and standards and by accelerating existing efforts that make it easier for people to partake. The idea behind health citizenship is to accelerate health-citizen recruitment for clinical trials, which is a critical barrier to accelerating clinical research, and to increase the representation and diversity of participants. Health citizenship can also help to design clinical trials to address the questions of most importance to patients and to use innovative trial designs and technology (for example, telemedicine, mHealth apps, and clinical trials such as Lung-MAP) to lower the logistical hurdles and burdens of participation in clinical trials.

As one interviewee told us, "People underestimate, and the system underestimates, how hard it is [for a patient] to get through a clinical trial"; another said, "It's time to set a new social norm on being involved in clinical research."

DATA SHARING AND OPEN SCIENCE

We heard a lot from our interviewees about the need to share data across institutional lines and with study participants striking at the core values of open science. As Thomas Jefferson famously said, "An informed citizenry is at the heart of a dynamic democracy." If we are to democratize research, we must put the very people it is meant for to serve at the center.

The federal government has declared that we have a right to the information in our electronic health records, but first, we need access. Then, we need to exercise that right to our information. Last, we have the responsibility to share our data for the collective good.

The 21st Century Cures Act (https://congress.gov/bill/114th-congress/house-bill/34/text) gives the U.S. Department of Health and Human Services the authority to investigate the blocking of health information and to levy civil fines against violators. This should help to stop the practice of erecting inappropriate barriers that prevent the movement of health data out of electronic health records and other information technology (IT) systems. We also need the U.S. National Institutes of Health and the U.S. Food and Drug Administration to strongly enforce the current law that requires clinical trial data to be deposited in ClinicalTrials.gov (*1*, *2*).

HEALTH IT ADVANCES

The federal government has made major investments in the expansion of health IT and data infrastructure projects over the past decade. Data infrastructure has been a major focal point of several marquee federal research initiatives, including the Cancer Moonshot, the Brain Research through Advancing Innovative Neurotechnologies Initiative, and the Precision Medicine Initiative's® All of Us℠ research cohort. We must not let these investments go to waste, but instead, continue to build and improve upon this important work. Infrastructure may not be sexy, but it is critical to health citizenship. There was tremendous interviewee excitement for the

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ways in which digital technologies and the Precision Medicine Initiative will allow patients to engage with their health data in new ways. As Sharon Terry has pointed out, "The networked information age allows for crowdsourcing and information liquidity, enabling everyone to play a part." (*3*)

There is ongoing discourse about providing patients with more control over their health data, which is good news for both patients and research. In one survey, more than 70% of patients were willing to share their personal health information so that researchers can better understand diseases and develop new ways to prevent, treat, and cure them (*4*). Rx for Innovation interviewees from many sectors called for an end to data hoarding. One patient advocate lamented, "Our data are not integrated! We can't build on the success or knowledge of the work that came before us." This is not just the right thing to do, it is the way we will drive innovation. Patients having control of their health data is a perfect way to help these citizens be more actively engaged with their health, to increase participation in clinical trials, and to produce better educated patient populations; these initiatives move the R&D enterprise forward, toward the medical interventions and preventive health strategies that citizens want and need.

We must make sure that the social contract of health citizenship is indeed a two-way street—that patients become engaged and that the system makes it easier for them to do so. This mutual respect, commitment, and engagement will improve the overall system, resulting in better medical products and more patients having access to them. As an industry expert told us during an Rx for Innovation interview, "We have everything we need to complete a revolution in R&D, and the revolution will be driven by patients."

–Margaret Anderson

REFERENCES

1. "Law ignored, patients at risk," *STAT News*, 13 December 2015.
2. M. L. Anderson, E. D. Peterson, Compliance with results reporting at ClinicalTrials.gov. *N. Engl. J. Med.* **372**, 2370–2371 (2015).
3. S. F. Terry, The study is open: Participants are now recruiting investigators. *Sci. Transl. Med.* **371**, eaaf1001 (2017).
4. Research!America, National Poll: Clinical Research (2013); www.researchamerica.org/sites/default/files/uploads/June2013clinicaltrials.pdf.

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