WOODROW WILSON CENTER JULY 2018

The Rise of the New Bio-Citizen

Ethics, Legitimacy, and Responsible Governance in Citizen-Driven Biomedical Research and Innovation

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Workshop Report

Stories of bio-citizens operating outside the traditional biomedical research community have astonished some and empowered others. Such a disruptive movement offers the lay public new opportunities to guide the direction of biomedical innovation and enables individuals to generate and mobilize new knowledge. The *Rise of the New Bio-Citizen* workshop gathered key actors in citizen-driven biomedical innovation and advocacy, democratized biology (community bio-labs), and policy experts. Participants held an open discussion centered on the ethical, safety, and governance issues related to citizen-driven biomedical research. Collectively they discussed codes of conduct, guidelines, and policies that address governance issues identified in the Citizen Health Innovation Report and identified barriers and ways to enable increased participation amongst bio-citizens. Appendix 1 provides the agenda, participant list, and discussion prompts that were used for the workshop. This workshop report provides an overview of those discussions.

1

BARRIERS

- Financial Stability
- Liability
- Lack of infrastructure for engagement
- Will to change

2

OPPORTUNITIES

- Public database of ideas
- Social license to operate
- Innovation pipeline
- Leverage expertise across disciplines & communities

3

WAYS FORWARD

- Build collective responsibility
- Develop centralized decentralization to gain legitimacy

Don't Favor the Rules That Don't Apply to Me

Regulations do not have to be a barrier to innovation.

Centralized Decentralization

Community bio-labs and health incubators could serve as institutional liaisons for bio-citizens navigating the regulatory ecosystem.

Bio-Citizen Toolkit

A compilation of resources for future bio-citizens that will become a living toolkit that evolves as the community of bio-citizens evolves.

Executive Summary

We need empowerment, but also greater collective intelligence.

Under the designation "patient-led research" (PLR) or "citizen-driven biomedical research," citizens, patients, and families have increasingly become the leading force in the initiation or conduct of health research projects, pursuing a range of activities from analyses of genomic data for diagnosing rare diseases, identification of potential therapeutic drugs, organization and crowdfunding of clinical trials' cohorts, and even self-surveillance or self-experimentation. Many of the participants in citizen-driven biomedical research are patients and families confronted with a condition that is the subject of their research, therefore facing new epistemic and governance challenges, and often testing the ethical and regulatory limits within which health research has traditionally operated.

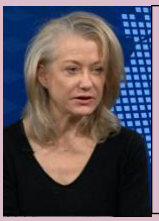
This new form of research where citizens and patients are the primary producers and mobilizers or instigators of knowledge promises to break new ground in underserved health domains, but also suffers from a lack of legitimacy when it comes to assessing the quality of patients' experiential data. Moreover, this endeavor gradually transfers the responsibility to preserve safety and ethics to lay experts, probing new ethical matters of concerns – from blurring boundaries between treatments and self-experimentation, peer-pressure to participate in trial, exploitation of vulnerable individuals or third parties (children), to a lack of regulation concerning quality control and risk of harm. Very little research currently focuses on adequate ways to adapt or design responsible governance and ethical standards tailored to citizen-driven biomedical research.

Notwithstanding ongoing challenges, we should not simply disregard medical research conducted outside of traditional institutions as de facto less safe, less reproducible, or unethical. Patients often have in-depth experiential knowledge of their conditions along with a vested interest in making sure that a treatment or device will be effective, safe, and beneficial. Yet, facing regulatory uncertainty, they might not overcome the "chill factor" – a phenomenon described by citizen scientists and DIY inventors as the fear to confront regulators by sharing the recipe for a new invention. The press has recently covered cases of biohackers who self-experimented with unregulated gene-therapies. However, the stories encountered in community bio-labs, such as Biocurious and Denver Bio-labs, are different: mentors, amateurs, and students want their proof of concept to be safe and reproducible, achieving specific standards in the research processes and evidences they rely on.

A PROFILE OF BIO-CITIZENS

The attributes of a new "bio-citizen" in a "citizen-driven biomedical research" scenario looks like this: scientists, patients, congressmen, employees — everyone — will be monitoring the DNA of their own bodies, including markers of health and disease, on shared cloud labs. Portable genome sequencers, the size of a USB stick and connected to our smartphones, would also be integrated to our most strategic technical systems, including agro-food facilities, airports, and hospitals. In their homes, individuals would have access to liquid biopsies – blood tests that could track their most vital biomarkers and identify the pieces of DNA shredded by a cancer tumor or a viral agent at an early stage. Devices in their homes and worn on their bodies passively collect vital signs, sleep, and manifold behavioral and environmental data. Algorithms are trained to analyze individual datasets against population-level data, and to trigger alerts when necessary, either to reinforce positive trends or intervene in negative ones. If millions of bio-citizens were streaming data to the cloud, they would build the most powerful data set for preventive and precision medicine the world has ever known. (Eleonore Pauwels (2017). "The Internet of Living Things," Scientific American (25 July)).

Matt Might, *Precision Medicine Chair, University of Alabama and Citizen Innovator*



Anna McCollister-Slipp, *Chief Advocate for Participatory Research. Scripps Translational*

Video Interviews

David Kong, *Director, Community Biotechnology Initiative, MIT Media Lab*

Sally Okun, *Vice President, Policy and Ethics, Patients Like Me*

Perspective from Regulators

Using patient experience data is not unprecedented in drug regulation, as FDA approved Exondys 51 in September 2016 in part utilizing this type of information. Legislators describe "real world evidence" (RWE) in Section 3022 of 21st Century Cures as any drug performance data which does not come from randomized control trials. This information can originate from "ongoing safety surveillance, observational studies, registries, claims, and patient-centered outcomes research activities." Notable examples of RWE include electronic health records, personal health devices and/or apps, billing records, and social media. As defined by 21st Century Cures, RWE exclusively applies to drug regulation (potentially including regenerative therapies). This type of data would aim to enhance the generalizability of clinical trial findings. (Sherman et al. 2016, p. 2293)

21st Century Cures directs FDA to create a trial framework for implementing the use of real-world evidence (RWE) by the end of 2018. This draft framework would use input from the public (e.g. industry, academia, patient groups) and apply only to drugs. FDA will then publish guidance on when RWE will be applicable and how to best collect this data. However, in July 2016 the FDA published draft guidance on utilizing RWE in medical device oversight[1], suggesting RWE could become applicable across FDA regulation. RWE may help address issues with current clinical trial designs, which require large patient cohorts and high costs but still lack generalizability. (Sherman et al. 2016, p. 2293; Pazdur 2016) However, existing sources of RWE were not designed to aid regulatory decision making and could present analytical challenges. (Sherman et al. 2016, p. 2293) Patient experience data may be able to serve a similar role, but limited literature exists on the potential risks and benefits of using patient experience data in regulatory approval.

Interestingly, 'patient experiences and perspectives,' which the FDA has been tasked with measuring and analyzing, does not seem to align with citizen-driven biomedical research and patient-led health innovation. Since RWE applies to drug regulation, many of the case studies in this report would not fall under this classification of research because not all citizen-driven biomedical research aims to produce drugs that will require regulatory approval. At best, the definitions of these two terms – RWE and citizen-driven biomedical research – do not align; at worst, the FDA has been tasked with measuring and analyzing only a small subset of patient-led health innovations within the broader scope of citizen-driven health research. Even more recently, in November 2017, the FDA released information about the self-administration of gene therapy. (FDA 2017, *Cellular & Gene Therapy Products*) According to that statement the,

> "FDA is aware that gene therapy products intended for self-administration and 'do it yourself' kits to produce gene therapies for self-administration are being made available to the public. The sale of these products is against the law. FDA is concerned about safety risks involved. Consumers are cautioned to make sure that any gene therapy they are considering has either been approved by FDA or is being studied under appropriate regulatory oversight." (Ibid.)

Based on the statement above, the FDA's primary concern regarding DIY gene therapy kits does not seem based on consumer safety; rather, their concern seems to be with the sale of such kits to consumers. This theme was present throughout the workshop discussion.

Breaking Barriers to Innovation

The topic of barriers to citizen-driven biomedical innovation were categorized by regulatory, methodological, and cultural. During the workshop, the project leaders posed a series of "what if…" questions in preparation for building a living bio-citizens toolkit.

What if…you could collaborate with traditional scientists and regulators?

[1] U.S. Food and Drug Administration, (2016), "Use of real world evidence to support decision-making for medical devices," Retrieved on June 4, 2017 from: [https://www.fda.gov/ downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm513027.pdf]; Hills, B. & Zegarelli, B. (2016), "21st Century Cures Act requires FDA to expand the role of real world evidence," Retrieved on June 4, 2017 from: [https://www.healthlawpolicymatters .com/2016/12/19/21st-century-cures-act-requires-fda-to-expand-the-role-of-rwe/].

What if…bio-citizens and regulators had a clear line of communication? Would this alleviate some barriers to innovation?

What if…there were no barriers to innovation. What would that look like?

What if…you could create a governance system that would work for bio-citizens? What would that system look like?

What if/are…there were economic incentives for bio-citizens?

"Don't Favor the Rules that Don't Apply to Me"

A recurring theme throughout the discussions was, broadly speaking, about regulations. What are the regulations that govern the bio-citizen? *Should* there be regulations that govern the bio-citizen? Are regulations preventing or discouraging more bio-citizens from participating, or coming out of the shadows? How can the bio-citizen better understand the goals of regulation and how can the regulator better understand the goals of the bio-citizen? These questions around governance and regulatory systems require further discussion, but the overall sense from the participants is that this doesn't have to be a barrier to innovation. Providing accessible resources for the bio-citizen to gain access to regulators in order to help reinterpret the regulations to fit their unique circumstances will help mitigate the potential for regulations to build barriers.

The chart below is one example of an accessible resource that may benefit bio-citizens, community bio-labs, and regulators. Community bio-labs have the potential to prototype and experiment in an environment with ongoing risk and safety oversight. In this way, community bio-labs could be a bridge between individual bio-citizens and regulators by serving as a safe-space to experiment and test governance systems.

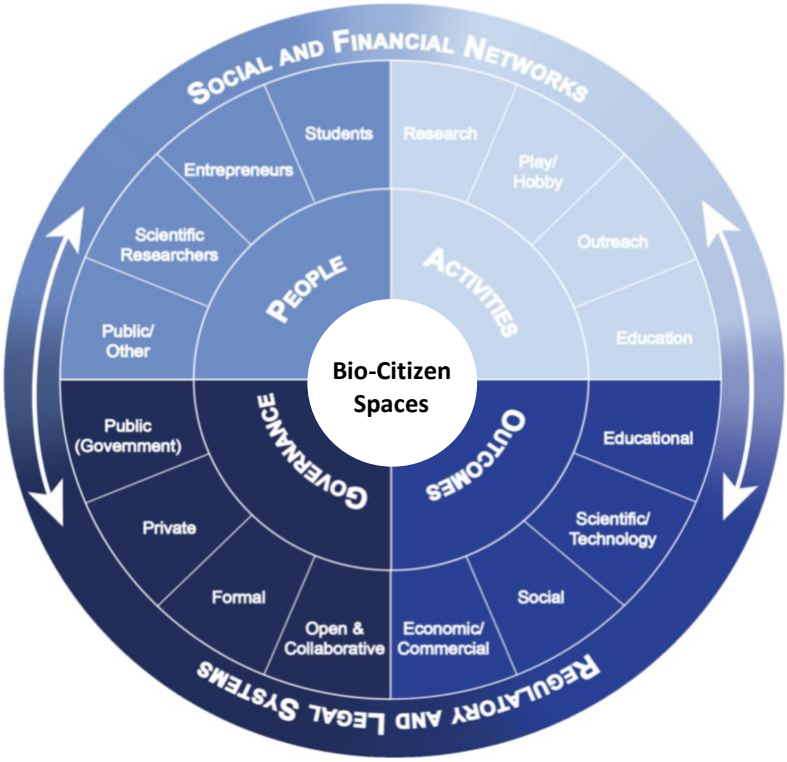


Figure 1: Context and Constraints in Bio-Citizen Spaces

Adapted from:
Context and Constraints in Biohacker Spaces
Jeremy de Beer and Vipal Jain, (2018). "Inclusive Innovation in Biohacker Spaces: The Role of Systems and Networks," *Technology Innovation Management Review*, 8:2 (February): p. 28.

Community Bio-Labs: The Bridge Between Bio-Citizens and Regulators

Community bio-labs and accelerators such as incubators are situated well to serve as a bridge between bio-citizens and regulator for at least three reasons. (1) Community Bio-labs are educational hubs and provide necessary connections to potential mentors and collaborators; (2) community bio-labs could serve as ramps to innovation; (3) Community bio-labs could help create centralized decentralization by creating space for community-biosafety officers, which would act as a liaison between communities and provide ethical, safety, and regulatory resource support.

1. Community Bio-labs as Educational Hubs

Biocurious is a community bio-lab in California that is dedicated to providing a working space for anyone to have access to equipment, materials, and mentorship from accomplished scientists and researchers. For example, Elodie, a senior at Los Altos High School, has one of the most unique after-school activities for students her age – she walks to Biocurious, a community-based bio lab, where she is conducting research that could save her brother from painful medical treatments. Growing up, Elodie witnessed her brother suffering from sudden crises called pneumothoraxes, triggered by a disease where a lung collapses and separates from the chest wall. In severe cases, the best-in- class treatment is to create scar tissue on the chest wall as a grip to keep the lung in place. To say the least, it's invasive and painful treatment. Elodie, not wanting to see her brother suffer through either the disease itself or the best-in-class treatment, she set off to Biocurious to develop her own vision, her own innovation, a sort of biological velcro. Biocurious was the perfect place for her, she had access to bioprinters, mentors, and pretty much everything she needed into order to leverage the inner mechanisms of proteins to bind lungs to the chest cavity.

For weeks, Elodie searched through the scientific literature to find the proteins that are responsible for helping cells bind together. After narrowing down the search to a few prime candidates, she genetically modified them to enhance their binding effects. Her bio-community helped her make sure her proof-of- concept was reproducible by obtaining three optimally engineered proteins that bind very tightly to lung cells. Soon, she will start using Biocurious' bio-printer to print the engineered proteins on a molecular patch, a thin matrix of collagen to be placed between the chest and the lungs. Now, Eric Espinoza is helping her to identify the best substrate for what she calls her biological double-sided tape. Elodie has also not encountered specific regulatory requirements yet, but she will likely encounter them because her goal is to develop a clinical or surgical application, a better treatment for her brother than what is currently available. She is on a time crunch. Luckily, her mentors at Biocurious have helped her to make sure all of her ducks are in a row when she attempts to acquire regulatory approval for her novel pneumothoraxes treatment. She has already made sure her proof-of-concept is reproducible, which is the first thing she would be asked for if she tried to get this into a clinical trial.

2. Community Bio-labs and Centralized Decentralization

Expanding the health innovation platform to include the bio-citizen raises the issue of informed consent in a novel way. Participants wrestled with the concept asking questions like:

- Is bringing consent into the governance process too burdensome?
- What are the "right" levels of consent? Are there different levels of consent in different situations? If so, where does self-experimentation fall on this spectrum of consent?
- How much does one need to know to understand in order to give consent? How do we deal with known unknowns?
- How should we deal with incomplete information/knowledge transfer? This was particularly relevant towards individual's medical/genetic data points collected and shared with others. But questions remain as to who the *others* are.
- Are the operating and rigid institutional framework of scientific and professional values problematic?
- Is the systematic institutionalization of ethical values problematic?
- Could you develop a citizen service provider for informed consent, a centralized institutional review board (IRB) that operates via decentralized community labs/IRBs to increase access?

- If you are filming and broadcasting everything that you are working on and/or doing, are you providing a resource and therefore a need for consent from those receiving that information? This was an issue that needs more thought and exploration.
- Where does the burden of consent and liability lie?

The discussion around adequate informed consent evolved into a discussion about institutional review boards (IRB) and how such a system might operate in the age of the bio-citizen.

- What is the practicality of such a system?
- Are there different levels of approval that should be applied to the bio-citizen?
- Would such a system provide a level of legitimacy for the bio-citizen?
- Do rigid institutional governance frameworks prevent permissionless sandboxes (i.e., permissionless innovation silos)?
- Do permissionless sandboxes hinder the establishment of a social license to operate for bio-citizens?

One idea was whether you could design a "peer to peer" IRB system, or more basically, provide access to the expertise and information that underwrites the spirit of what a traditional IRB does. A similar type of project was developed around biosafety for the DIYbio community with its *Ask a Biosafety Expert* web portal. Whether this type of system could work for issues that an IRB handles requires further thought and deliberation. For instance, could community IRBs lead to unconventional or non-traditional studies? Is approving unconventional and non-traditional experiments necessarily a sign of permissionless innovation?

One critical aspect is the liability associated with programs like this. Experience from the *ask a biosafety expert program* suggests liability insurance is both needed and difficult to acquire without dedicated funding, which bio-citizens don't always have. How might bio-citizens who crowdfund the resources necessary to innovate acquire liability insurance? In addition, this type of program would need some semblance of infrastructure and management in order for it to be useful for the community.

Other ideas that emerged from this discussion revolved around developing ethical and safety workshops/curriculums aimed at bio-citizens, incubators, and community labs. These were also seen as potential capacity building opportunities for community biology labs and health incubators. *Public Responsibility in Medicine and Research* was presented as a model that could be used.

3. Community Bio-labs as Ramps to Innovation

There was a sense amongst the participants that we need a better understanding of the underlying ethical issues associated with the bio-citizen and creating opportunities for inclusive innovation (de Beer, 2018). Issues such as treatment vs enhancement or self-experimentation vs survival were discussed, and consensus was reached on the need for conceptual clarification. It was felt that we have little understanding "on the individual" when we abstract these issues to society at large, particularly when discussed under the concept of social license to operate. But, while many of the ethical issues focused on the individual, it was suggested that the issue be expanded beyond the individual to include public health, environmental health, and the impact on public science at large. This discussion led us to contemplate issues of paternalism, who gets to control another person's acts; who is the real villain? The person who may engage self-experimentation or the person trying to stop any potential harm incurred? The lines are fuzzy particularly when people, or the individual, thinks they are helping.

One suggestion was for the community to address, or at least better understand, the underlying ethical issues associated with the bio-citizen first. It was suggested that by doing this first you could then begin to unpack how the regulatory structure affects the bio-citizen and evaluate how these ethical issues can guide what's happening, not stand in the way. It was felt that not meeting these ethical standards could cause others in society to reject what the bio-citizen might be doing and place societal roadblocks to the innovation platform or inclusive innovation.

While we were focused on increasing access to the innovation platform, it was also suggested that scientists, and therefore the bio-citizen, need to have some friction in the sense that there are issues and understandings that are needed beyond the technical.

Technologists and scientists are focused on a specific kind of knowledge generation and are not well suited, in the context of time, education, and influence, to also assess and address any potential ethical issues. It was mentioned that having ethicists working alongside scientists and technologists may help alleviate this tension while not completely getting rid of friction between the two groups. Interdependent issues encompassing ethics, social license to operate, and legitimacy were major underlying themes discussed throughout the workshop.

A social license to operate "is an informal agreement that infers ongoing acceptance of...a project by a local community and the stakeholders affected by it." (Gallois et al. 2017) Though a social license to operate has typically been associated with industrial and energy industries (Ibid.), the concept elicits opinions about who/when/if you ask permission and whether acquiring a type of social license to operate establishes legitimacy. The "expression refers to mainly tacit [or, experiential] consent on the part of society toward the activities of business (or in our case the bio-citizen) …it constitutes grounds for the legitimacy of these activities" (Demuijnck, 2016). A social license to operate does not necessitate or prevent permissionless innovation; rather, a social license to operate allows community bio-labs and bio-citizens to innovate in safe innovation spaces with ongoing risk and safety oversight. While establishing a social license to operate may help to break barriers to bio-citizen innovation, some questions remain in the social context. For instance, what is the entry point? Is it a social license, a market license, an ethical or legal license? When do you ask for permission? Whom do you ask? These were some of the central questions the group discussed around how to build trust and legitimacy for the bio-citizen.

Finding the narrative story that shows the social good was suggested as a way to address this in part - you have to demonstrate the value of innovation for and by the bio-citizen. However, how do we establish communication between communities in order for them to understand what they are getting in return (particularly when sharing data)? How do we find the incremental value in bio-citizen innovation? How is that value or equity going back to the individual or community at large? Issues of equity and privilege are also important to recognize. For instance, some bio-citizens performing innovations with diseases, and innovations around those diseases, might not have the means to turn that into a business or gain access to the results of having participated. Moreover, that might not even be their end-goal. So, how might bio-citizens study rare genetic diseases and innovate without having to also become an entrepreneur?

The bio-citizen and the societies in which they are apart will need to define what a "social license to operate" means to them, particularly in a health context. How will it be measured since it will not be universal? It was suggested that these "social licenses" would need to be applied differently in healthcare. There was a sense amongst the participants that we need to collectively shift the urgency towards these issues if we want to build an inclusive innovation platform for the bio-citizen. In part because our sense of agency is declining. While clinicians are trusted, institutions are not and there is even lower trust in government. At the same time, some participants felt that people/publics may be scared of the bio-citizen (DIYbio) and that increasing engagement channels (i.e. DIYbio days at local hospitals) could be an avenue to increase trust amongst these groups. Having bio-citizens coming in to answer the questions for themselves could help move towards a better understanding of the social good. The positive aspect of permissionless innovation is the notion that we should be able to experiment in safe innovation spaces. But, how do we protect human rights in an ecosystem of permissionless innovation?

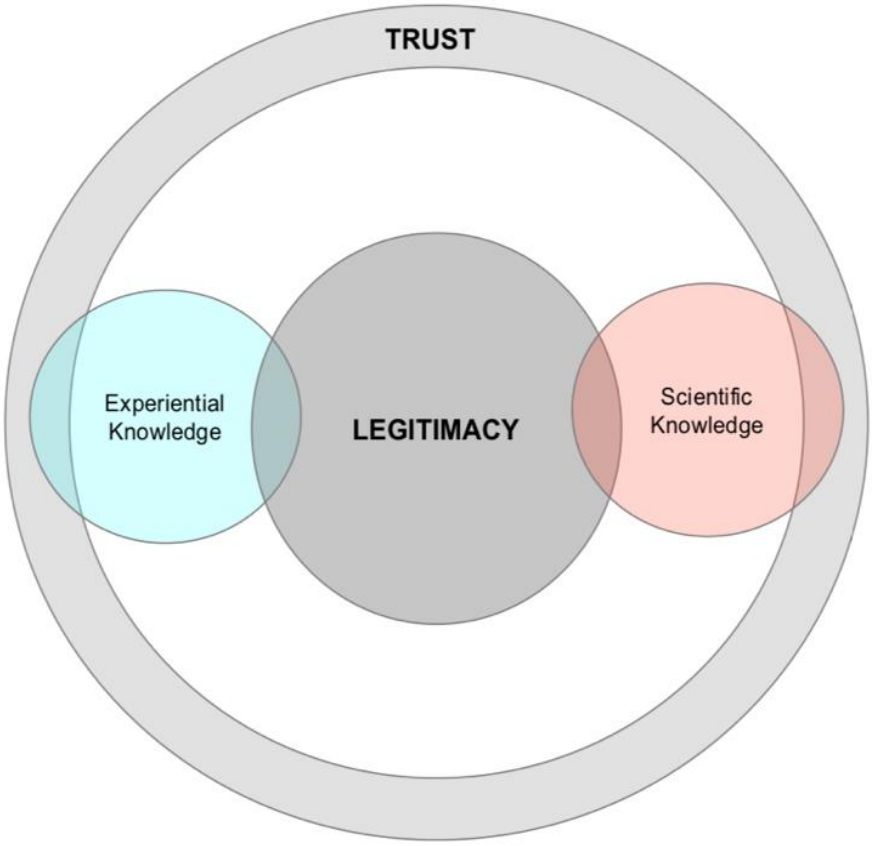
A Living Bio-Citizen Toolkit

It has become clear that certain barriers and opportunities for innovation as well as governance and ethical issues play a role in participatory health research and innovation – even if traditional regulatory approval does not. Specifically, barriers to innovation include, but are not limited to: the inability to quit one's job to dedicate time and energy to finding alternative treatments, cures, and ways to navigate the medical/clinical field; the high cost of regulatory approval; and the cost and complexity of acquiring the necessary knowledge for medical and technological literacy, which may or may not be seen as legitimate by traditional actors.

Traditionally, knowledge legitimacy has been tied to scientific knowledge; but citizen health innovators are beginning to change that paradigm and inject their experiential knowledge into biomedical research. Before bio-citizens will be seen as legitimate health

innovators in the eyes of the traditional scientific and policy communities, they will need to overcome some obstacles and gain the trust of scientists and regulators.

Towards the end of the workshop, participants were asked to write down ideas for what should be included in a tool kit for current and future bio-citizens. What should we put in it? What do you wish you would have had? What would you leave out? Many of these ideas stemmed from Boxes 1-3: Opportunities and Challenges. Building off those ideas and the discussions throughout the workshop, researchers and bio-citizens have begun compiling a tool kit for future bio-citizens that we hope will become a living tool-kit that evolves as the community of bio-citizens evolves. The goal is to develop engagement channels between patients-innovators, crowdfunders, ethicists, and regulators to design adaptive oversight mechanisms that will foster a culture of empowerment and responsibility. Concretely, the authors of this report started building a taxonomy of different forms of innovations where you would also find, in parallel, an assessment of the risk-benefit trade-off defined in collaboration between bio-citizens and regulators.



1
What do current bio-citizens wish they'd had?

Ramp to Innovation Platform

Public database of ideas

Open science framework registries

Collective Responsibility in Non-Traditional Research Settings

DIY ethics curriculum

Demonstrable Value

Find incremental value

Communication between communities to understand benefit-sharing (particularly when sharing data)

Equity Distribution

Understand Regulatory Goals, Don't Just Ignore Them

Leverage expertise across disciplines and communities

Method for Gaining Trust & Legitimacy

Speak truth to power

Will to change

Speak their (i.e., regulator, traditional medicine) language

Collective Urgency Shift

People are participating in their health more than we think

Create regulatory thread throughout R&D

2
What do future bio-citizens need in their toolkit?

Understanding of the Underlying Ethical Issues from the Report

This must be done first, before it is possible to see how bio-citizens fit into the existing regulatory structure

How can these ethical issues guide bio-citizens without creating undue barriers?

Mechanism for Ensuring Quality Control of Data

Sharing of knowledge, data, and protocols

Social License to Operate

Defined entry points to innovation safe-spaces like community bio-labs

When do you ask for permission and whom do you ask?

Identify ways social license to operate is granted in ways we are not typically used to

Centralized Decentralization

Get people in community bio-labs whose jobs are safety, ethics, and communication

Innovation infrastructure to keep growing

Building Blocks to Integrity

Sharing of knowledge, data, and protocols

3
What should be left out of the bio-citizen toolkit?

Rigid Institutional Frameworks

"Peer-to-Peer" register of ideas may help lower the barrier to entry

Traditional researchers and scientists have more funds, clout, etc., with regulatory agencies

Privilege

Every bio-citizen does not have the same finances, time, education, etc.

Ambiguity Between Bio-Citizens and Bio-Hackers

Bio-citizens are more attuned to following safety protocols, but have little access to regulators

Stigmatization of Bio-Citizens

Centralized Regulatory Institutions

Regulatory institutions should be adaptable to a variety of research settings beyond traditional laboratories

Capitalist-Approach to Biomedical R&D

Some begin research in response to undone areas of science, such as rare genetic diseases and n=1 diagnoses, which aren't viewed as profitable

By relying on this tool kit, next steps could be creating channels for crowdsourcing expert and tacit/experiential knowledge, reducing the ethics and legal uncertainty that patients face when funding, and sharing their protocols, data, or inventions. Broadly, this tool kit seeks to address the follow questions:

- How can we create a safe space for health innovators and community bio-labs to share and experiment with their data, value trade-offs and ethical concerns in ongoing conversations with regulators?

- How can regulators and crowdfunding platforms help bio-citizens modernize practices that will give legitimacy to their research, devices, and treatments?

Participatory biomedical research breaks when there is no means of ensuring quality of data, such as the data that is derived from person-generated data (e.g. the data produced by Dana Lewis' artificial pancreas) and self-reported data (e.g., the data on Crohnology.com). Yet, lack of quality control of data is one, but certainly not the only, concern related to citizen-driven biomedical research. Instead of trying to fit citizen-driven innovation into the existing regulatory framework, a more adaptive approach might help these citizens become literate in how to conduct research and help them identify the regulatory checkpoints.

One potentially useful tool for both bio-citizens and regulators might be Table 1. When bio-citizens and regulators communicate their needs, determining where a governance option may fall on the table below may help prioritize regulatory actions in a way that will not place undue burdens on bio-citizens. The goal should be to develop governance and regulatory mechanisms that fall within the gold bubble, which would be the interventions that have the greatest impact and high achievable.

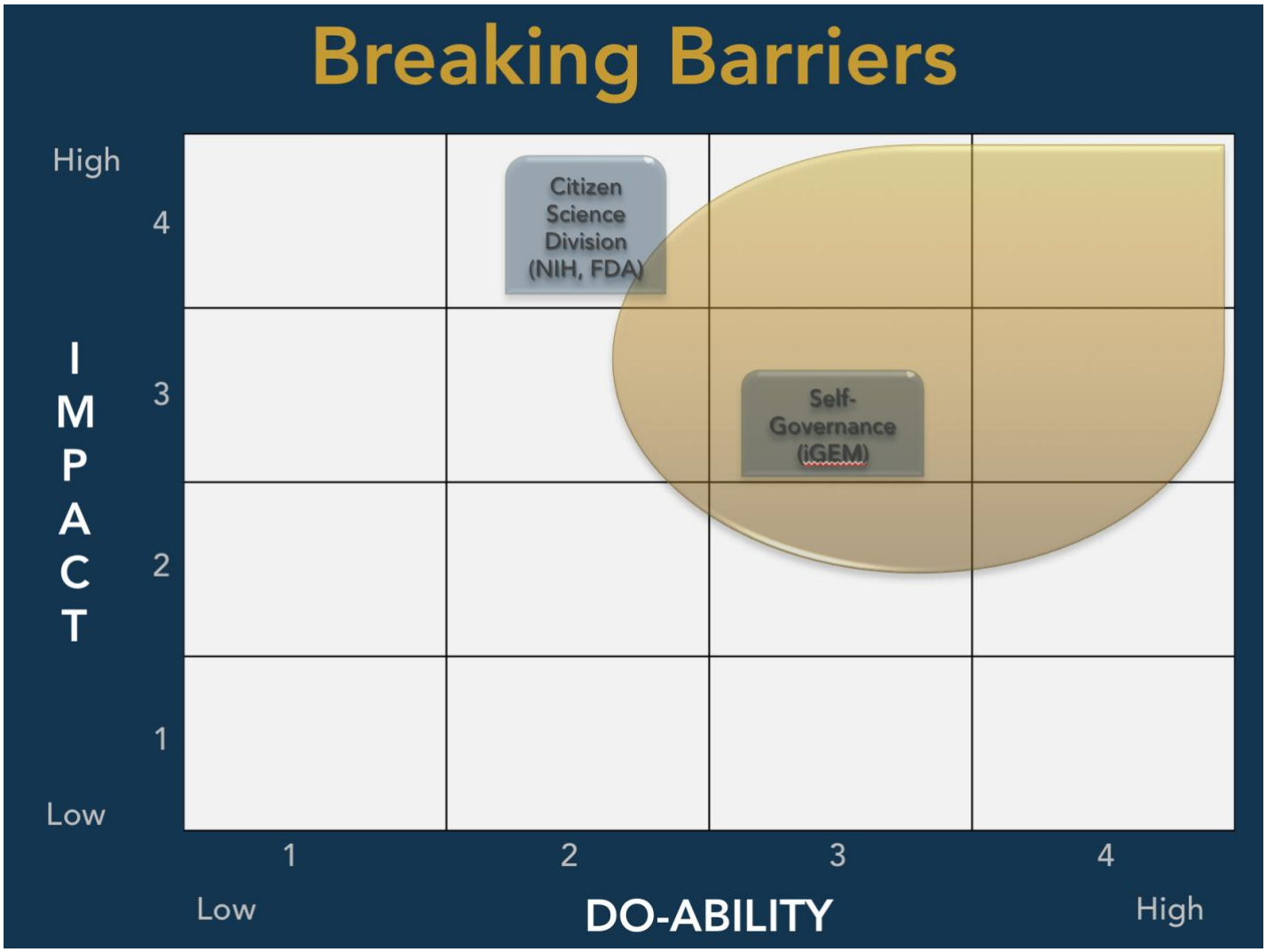


Table 1: Breaking Barriers, developed by the project team in preparation for the workshop.

Appendix 1

Agenda

DAY 1: March 12, 2018

On the first day of this workshop, participants and the project team will collaboratively diagnose and discuss the barriers to citizen-driven biomedical research. In the report, we have identified a host of issues around legitimacy, empowerment, experiential knowledge, privacy, self-experimentation and governance models, which will be used to help drive the discussion forward.

8:00am – 8:45am **Sign-In, Meet-and-Greet**

8:45am – 9:00am **Welcome & Introductions**, *Eleonore Pauwels*

9:00am – 9:30am **Project Overview / Levels of Discussion**, *Eleonore Pauwels & Todd Kuiken*

Project leaders, Eleonore Pauwels and Todd Kuiken, will kick off the discussion by providing an overview of the project and present a framework for the workshop discussion. This framework will consist of four levels: (Tech) open technology for acquiring and sharing data; (People) open collective intelligence platforms for sharing knowledge and research; (Rules/Culture) ethical, societal challenges and systems level barriers to open health; (Funding) how has the advent of crowdfunding platforms changed who/what/when/where/how open health innovation occurs. In this session, key graphs in the report (p 47-56) will be introduced to participants for further reflection and revision.

9:30am – 10:30am **Health and Data Pioneers**, *Matt Might & Anna McCollister-Slipp*

This will be the first of three innovation storytelling sessions. Health and data pioneers will describe their journeys, providing detailed first-person perspectives on the barriers and opportunities for biomedical research and innovation.

10:30am – 11:30am **Community Biolabs & Incubators**, *Joe Jackson, Eric Espinosa (Tentative), Heather Underwood, Tom Burkett, and David Kong*

The second of our storytelling sessions provide first-person perspectives from the community biolabs.

11:30am – 12:30pm **Accelerators**, *Sally Okun, Bernard Munos, and Susannah Fox*

This session will provide a perspective from those who have actively participated in capacity-building efforts for patients' involvement in precision medicine R&D and peer-to-peer health.

12:30pm – 1:30pm *Lunch*

1:30pm – 2:15pm **Imagination Incubator**: *David Kong, Jason Bobe, Amy Dockser Marcus, and Kristen Brown*

This session will consist of a facilitated group discussion led by David Kong (MIT Community Biotechnology Initiative), Jason Bobe (Mt. Sanai Sharing Lab), Amy Dockser Marcus, (Wall Street Journal), and Kristen Brown (Gizmodo). This purpose of this session will be to share visions of the future of biomedical research and innovation – a real-time imagination incubator led by David and Jason ("What If") – and reflections from journalists/thinkers who have analyzed in-depth this emerging research ecosystem.

2:15pm – 2:30pm **Part I Wrap Up**, *Eleonore Pauwels & Todd Kuiken* (workshop report)

Pauwels will jumpstart the afternoon dialogue with a brief summary of the morning's session and proving context for the afternoon's structure. The following dialogues will be primed by posing key questions to the group, which will be addressed in the following sessions. What are the barriers to citizen-driven biomedical research? Are they:

- Regulatory (e.g., "strong rules and policies" or "this is how it is in the book");
- Methodological (e.g., how do you curate data for such a citizen-driven effort; or
- Cultural (e.g., "what about the languages we use?")?
- What does empowerment mean in the US biomedical & research culture?
- How are these notions evolving? How should they evolve?

2:30pm – 3:30pm **Introduction to the Governance Issues and Responsibility,** *Health Innovators, Pioneers, and Community Biolabs*

Within a facilitated group discussion, health innovators, pioneers, and individuals within community biolabs will share their unique perspectives on the barriers and obstacles they faced throughout their biomedical research and innovation journeys. Regulators will share their regulatory frameworks and discuss what constraints and/or laws might raise barriers and obstacles. The aim is to ensure an understanding between innovators and regulators, identify "chill factors", and explore how to encourage collaborations between

citizens, patients, and the traditional research and regulatory communities. On what mechanisms and issues can we work and think together? The project team will present the case study flowcharts (p47-56) and Table 3 from the report for critique by the workshop participants.

3:30pm – 4:00pm *Break*

4:00pm – 4:45pm **Introduction to the Ethical Issues and Legitimacy**, *Regulatory Perspectives*

After a brief break, the workshop will resume to discuss how bio-citizens could gain scientific and knowledge legitimacy – i.e., what citizens and patients need to do to show regulators and policymakers their research and innovations are legitimate. The project team will present Table 3 from the report for critique by the workshop participants.

4:45pm – 5:00pm **Day 1 Closing Remarks & Reflection**

In closing, the protect leaders will prompt participants to take a few moments for reflection and write 2-3 non-elucidated questions and/or goals on cards. These cards will be used the following day to spark imaginative approaches to overcoming the obstacles in citizen-driven biomedical research.

5:00pm – 6:00pm *Reception & Video Interviews with Pioneers*, The Woodrow Wilson Center

DAY 2: March 13, 2018

9:00am – 9:15am Welcome & Day 1 Summary, *Eleonore Pauwels & Todd Kuiken*

Day 2 will begin with the project team welcoming participants and prepare for the capacity building aspect of the workshop. Eleonore and Todd will briefly overview the discussion from Day 1. In doing so, they will reiterate the goal of the workshop: to discuss ways forward that will increase collaboration between citizens, patients, scientists, and regulators while fostering legitimacy, patient empowerment, and responsible innovation. One perspective Eleonore wants to explore is how community bio-labs could become an empowerment incubator for citizens conducting biomedical research and a bridge with regulators.

9:15am – 10:00am *Barriers to Citizen-Driven Biomedical Innovation*

The first group dialogue will focus specifically on the barriers to citizen-driven biomedical research. The concept of this session is to generate imaginative ways for overcoming barriers and identifying opportunities for health innovators and pioneers in biomedical research. For instance:

- How might we foster new collaborative efforts between citizens, patients, scientists, and regulators?
- How can we create new collective platforms for legitimacy?

10:00am – 10:45am *Governance Models*

The second group dialogue will focus specifically on potential adaptive governance models for citizen-driven biomedical research. The concept of this session is to generate imaginative ways for questioning, modernizing or reconsidering legitimate rules of involvement for citizen bio-scientists in the biomedical research and innovation enterprise. For instance:

10:45am – 11:15am *Break*

11:15am – 12:30pm *Role of Community Bio-labs: Bridges between Citizens, Patients, Scientists, and Regulators*

The final group discussion of the day will focus on the role of community biolabs in the effort to foster legitimacy, patient empowerment, and responsible innovation.

12:30pm – 12:45pm Conclusion & Closing Remarks, *Eleonore Pauwels & Todd Kuiken*

In closing, Pauwels and Kuiken will provide a brief wrap up of the workshop and promote the project's vision to establish an imagination incubator. In service of this aim, the workshop will close with a list of ways forwards and next steps for stakeholders.

Other round of video interviews with Health Pioneers, community bio-labs leaders, policymakers, and others stakeholders

Participant List

David Kong, *Director, Community Biotechnology Initiative, MIT Media Lab*

Sally Okun, *Vice President, Policy and Ethics, PatientsLikeMe*

Matt Might, *Precision Medicine Chair, University of Alabama and Citizen Innovator*

Magdalena Schoeneich, *Global Head of Takeda Digital Accelerator, R&D*

Bernard Munos, *Founder, InnoThink Center for Research in Biomedical Innovation (Faster Cures)*

Elaine Johanson, *Director (acting), Office of Health Informatics, Food & Drug Administration*

Edward You, *Supervisory Special Agent, Weapons of Mass Destruction Directorate, FBI*

Anna McCollister-Slipp, *Chief Advocate for Participatory Research. Scripps Translational Institute, VitalCrowd*

Kathryn Harris, *Consultant on Biosafety Research, NIH Office of Science Policy*

Jason Bobe, *Associate Professor and Director of Sharing Lab at the Icahn Institute for Genomics and Multiscale Biology, Mt. Sanai School of Medicine*

Courtney Lias, *Director, Division of Chemistry and Toxicology Devices, Food & Drug Administration*

Joseph Jackson, *Co-Founder of Bio, Tech, & Beyond*

Susannah Fox, *Advisor to HopeLab Foundation, Hope for Henry, PatientsLikeMe*

Tom Burkett, *Founder, Baltimore Underground Science Space (BUGGS)*

Elizabeth Tuck, *Genetics and Education Fellow, National Human Genome Research Institute, NIH*

John Wilbanks, *Chief Commons Officer, Sage Bionetworks*

Katrina Theisz, *Program Analyst, National Cancer Institute, NIH*

Arno Klein, *Director of Innovative Technologies, Child Mind Institute*

Camille Nebeker, *Principal Investigator, Connected and Open Research Ethics (CORE), Assistant Professor in the School of Medicine, University of California-San Diego*

Carol Weil, *Program Director, Ethical and Regulatory Affairs, National Cancer Institute, NIH*

Kristen Brown, *Senior Writer. Gizmodo*

Rebecca Hong, *Program Analyst, National Human Genome Research Institute, NIH*