

Big Data for Patients (BD4P) Program

Big Data for Patients (BD4P) Program: Needs Assessment

The Reagan-Udall Foundation for the FDA seeks your input on a new data science training program, "Big Data for Patients" (BD4P), for patients and advocates.

Based on RUF's work with patient advocates in our projects and programs, we know that data science ("Big Data") is a challenging topic. Without training in this rapidly evolving and complex area, patient advocates are not as likely to participate fully in research, policy, and funding decisions around Big Data.

Big Data efforts are working to leverage many different kinds of health data from many sources - from electronic health records (EHRs) and electronic medical records (EMRs) to patient-reported outcomes (PROs) and physicians' notes - to help inform and improve patient care. RUF's new program will serve to empower patients and advocates by enhancing data science literacy and critical appraisal skills.

BD4P will be developed in a collaborative manner to ensure that it meets the needs of patients and key stakeholders. The first step will be an initial needs assessment to gather input on prioritization of program content. We would greatly value your input!

Background

* 1. What type of organization do you work for (or represent)?

- Government
- Academic
- Industry (biopharma, bio IT)
- Not-for-Profit
- Patient/Health Advocacy
- Research Organization/Institute
- Other (please specify)

* 2. What is your primary area of work?

- Clinical Care
- Biomedical/Clinical Research
- Drug/Device Development
- Bioinformatics/Biostatistics
- Computer Science
- Health Policy
- Patient Advocacy
- Regulatory Science
- Other (please specify)

3. What is your level of familiarity with data science/Big Data?

- Very familiar
- Somewhat familiar
- Not familiar
- Unsure

4. What is your experience working in data science/Big Data research?

- Currently work on a Big Data project(s)
- Previously worked on a Big Data project(s)
- Likely to work on a Big Data project(s) within the next two years
- No previous involvement, but am following this area closely
- No previous involvement, and am NOT following this area closely
- Other (please specify)

5. Describe your interest in the field of data science/Big Data.

6. Describe your role, or likely role, in Big Data health research (select all that apply):

- Funder
- Sponsor
- Advisor/Advisory panel
- Data science subject matter expert (e.g., bioinformatics, biostatistics, computer science)
- Clinician/Researcher
- Payer/Provider
- Policymaker
- Patient/Caregiver/Advocate (as a representative)
- Patient (as a participant and/or data provider)
- Other (please specify)

7. From your perspective, how can patients and advocates contribute to Big Data health research? (select all that apply)

- Project/proposal development
- Request for Application (RFA) development
- Participating on an application review panel
- Serving on a steering or advisory committee
- Serving as a member of a project working group
- Providing stakeholder input
- Research participant
- Testing tools designed for patient use
- Disseminating information about the project
- Unsure
- Other (please specify)

8. Please rank the following topics that you feel are most important to include as part of a patient training program in Big Data:

Definitely include Possibly include Do not include Unsure

Use of health data (e.g., understanding disease/disease progression, comparative effectiveness research; patient-centered outcomes research)

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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Different types of health data (e.g., EHRs, EMRs, patient reported data, "lab" data, clinical trial data)

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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Potential impacts (positive and negative) of Big Data on healthcare and health research

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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Ethical issues that both patients and researchers need to be aware of (including health data privacy and patient consent)

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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Use of patient-reported and patient-generated data (including mHealth and data from wearable health devices and social media) in health research efforts

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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Use of genomic data in personalized medicine efforts

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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How health data is used for safety surveillance

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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Common terminology and general methods used for data analysis

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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Understanding correlation vs. causation

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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Challenges of data sharing and data re-use

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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Other (please specify)

9. Please rank how important you feel certain skills are to have in order for patients and advocates to successfully participate in Big Data research efforts:

	Very important	Somewhat important	Not important	Unsure
Prior experience in data science initiatives	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Critical appraisal/evaluation skills	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Basic scientific literacy in Big Data topics	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Experience working with interdisciplinary teams	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Ability to identify/navigate opportunities to participate in Big Data research efforts	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Ability to recognize and communicate the potential impacts of Big Data for patients	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Other (please specify)

10. Please list your hopeful outcomes for the BD4P Program, and any additional comments you may have.

11. Are you willing to be contacted for additional stakeholder input?

Yes (if yes, please complete contact information below)

No

12. Please provide your contact information if you would like to be contacted for additional input on the development of this program.

Name

Email Address