



# White Paper: Exploration of the Development & Implementation of the Big Data for Patients (BD4P) Program

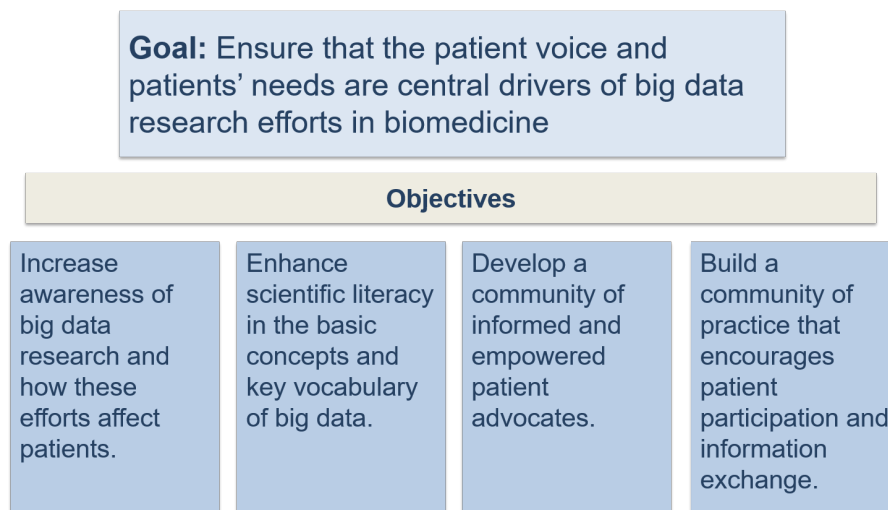
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## PROJECT BACKGROUND

Big Data for Patients (BD4P) was a two-year initiative to develop a model training program about the science and use of big data in healthcare targeted to patient advocates. The goal of BD4P was to help informed and empowered patient advocates understand what big data is, how it is being used in research and medicine, its promises and limitations and challenges, the impact on patients, and how patients can use this knowledge. The program was developed by the Reagan-Udall Foundation for the FDA (the Foundation) to empower advocates to participate in big data work by enhancing data science literacy and critical appraisal skills.

The emerging field of data science (also known as “big data”) is rapidly evolving, and the methods of accessing, integrating, and interpreting data are becoming increasingly complex. Big data efforts are working to gather data from various sources and formats – including electronic health records, electronic medical records, patient-reported outcomes, wearables data, and physicians’ notes – to help inform and improve patient care.

### Program Goal & Objectives



Program work began in July 2015 upon receipt of a Eugene Washington PCORI Engagement Award to support the development and implementation of the project. BD4P initiation was separated into 5 phases that covered development, design, and implementation of the program – 1) conducting a needs assessment/landscape report, 2) developing the curriculum and resources, 3) holding training workshops, 4) building a community of practice, and 5) evaluating the program.

The BD4P program was inspired by other advocacy training programs and designed to be conducted through in-person workshops, to facilitate dynamic interactions between participants and instructors, vigorous discussion and the identification of disparate viewpoints.

## Big Data in Health and the Role of Big Data in PCOR

Healthcare in big data encompasses numerous sources and types of data. Patients, hospitals, researchers, and physicians all create data that can be considered big data and can be used to create better healthcare outcomes.

### Examples of Healthcare Data Sources

Patient Records	Insurance Claim Data	Patient-Provided Input	Clinical Trials Data
<ul style="list-style-type: none"><li>•Electronic Health Records (EHRs)</li><li>•Electronic Medical Records (EMRs)</li><li>•Physicians' notes</li><li>•Lab results</li></ul>	<ul style="list-style-type: none"><li>•Billing information</li><li>•Payment history</li></ul>	<ul style="list-style-type: none"><li>•Patient-reported outcomes</li><li>•Social media information</li><li>•Wearables data</li><li>•Patient registries</li></ul>	<ul style="list-style-type: none"><li>•Outcomes</li><li>•Trends</li><li>•Populations</li></ul>

These disparate data sources lead to many uses that can benefit patients across the spectrum of healthcare, from recognizing disease trends to new treatments/products. In direct patient care, it can increase the coordination of care between providers by utilizing EHRs and other innovations. Big data can also lead to more comprehensive research, with findings informing a broad group of stakeholders.

This all circles back to the fact that big data in health is patient data, and therefore patients are the focus. Using big data allows a greater focus on individual patient needs, evidence-based care and personalized therapies over the traditional standard treatment. Big data supports increased patient-centeredness and promotes more opportunities for patient input and shared decision-making. This is a key component of Patient-Centered Outcomes Research, also known as PCOR. According to the Patient-Centered Outcomes Research Institute (PCORI), PCOR *“helps people and their caregivers communicate and make informed healthcare decisions, allowing their voices to be heard in assessing the value of healthcare options”* (Source: <http://www.pcori.org/research-results/patient-centered-outcomes-research>).

PCOR is used to ensure that healthcare decisions are made collaboratively with the patients’ best interests in mind – not only physical well-being but also mental and emotional. It takes into consideration the lifestyle and specific wishes of each patient (such as quality of life), rather than focusing on standard of care. PCOR also helps patients and physicians determine the best course of treatment by taking into account the availability of support and medical care.

PCOR enables a greater use of personalized medicine, in which treatments and care are tailored to each individual patient’s needs and wants versus traditional therapies. Patient-centered research conducted without patient input is detrimental and does not portray the true needs of patients. Therefore, patient engagement is not only important but necessary to advance PCOR.

Patients are a major focus of the use of big data in healthcare. It is becoming more commonplace to include patient input throughout multiple processes of the healthcare spectrum, including research, medical decision making, and treatments. There is a greater focus on innovation and finding advanced methods of care that align with patient preferences and individual characteristics. It makes sense that

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combining traditional research methods with PCOR can help studies become more comprehensive with more robust outcomes.

Patients can benefit from big data and help advance innovations by sharing data, outcomes, and experiences with other patients, physicians, and researchers. Examples of this are patient-focused data-sharing platforms in which patients upload their health information or participate in discussion boards and share information with other advocates. Another example of how big data and PCOR can benefit patients is by providing access to diverse disease information in areas such as rare diseases where the patient population may be small and spread out.

*Other examples of groups that may benefit from the use of big data and PCOR include:*

- **People with chronic conditions** – a large collection of multi-year data from disparate sources allows for the review of longitudinal effects and results
- **People with conditions that are not easily “tracked” by traditional methods** – wearables and patient-reported data allows for continuous tracking of symptoms, effects, etc.; i.e. Parkinson’s/neurological disorders
- **People with no existing conditions** – “healthy patients” who may not otherwise be submitting/collecting data; could help provide information on susceptibilities to certain diseases or conditions and could also be used as part of a comprehensive data set for certain populations

Without a doubt, big data can have a significant effect on patient lives, and patients can have a meaningful effect on big data. PCOR and an interest in patient-centricity drives the need for more patient involvement in big data work. Based on the Foundation’s work with scientists and clinicians and the involvement of patient advocates, we know that many people find big data difficult to navigate. Without training in this topic, patients and advocates may not feel comfortable or prepared for participating in this work or its design and evaluation. This is not only a setback for patient engagement, it is also a detriment to the research. Big data in medicine is patient data, so patient participation is vital to creating beneficial and patient-centered research initiatives.

### The Use of BD4P

The BD4P program and training workshops afford patient advocates an opportunity to collaborate with other advocates and learn from leaders and subject matter experts (SMEs) in advocacy and data science.

*Some ways that BD4P trainees could utilize the knowledge gained from participating in the workshop include:*

- **Providing scientific and technical knowledge** allowing them/their organization to navigate the landscape of big data
- **Applying evidence-based decision making** to key issues in big data research of relevance to them/their advocacy constituency
- **Partnering** with scientists, clinicians, and other to ensure patient-centeredness in big data research
- **Providing educated patient perspective** at public forums and in print on issue relating to big data
- **Participating** on scientific advisory committees, steering committees, review panels, study sections, etc.

## DEVELOPMENT

### Audience

Given this burgeoning interest in PCOR and efforts to make health care and medical research more patient-centered, it is critical that patients have an active role in big data research. The target audience for BD4P training were patients with a general understanding of advocacy, but who sought to acquire more specific knowledge and skills around big data in order to advocate and participate in projects supporting their disease community/patient constituency.

In-person training, like that developed for BD4P, incorporates conversation and discussion to clarify curriculum topics. Discussions are enriched through personal stories and experiences. Face-to-face interaction not only encourages sharing but also creates an experiential learning environment of common interests and solutions to problems. In-person learning enables trainees to engage directly with data experts and other advocates to ask questions and collaborate on existing issues.

### Stakeholder Engagement

Development of the program was collaborative, with patients and key stakeholders involved in shaping the program from prioritizing topics to input on program design, conducting the training program and evaluation. This ensured that the focus of the program was not only the impact of big data on patients, but also the impact that patients can have on big data research.

One way that the Foundation collected initial public input on program development was through a needs assessment survey conducted from August-October 2015. The assessment determined knowledge gaps and solicited input on program curriculum, format, and delivery. Information was gathered from a broad range of stakeholders on interests and priority topics. The results identified many topics but the three identified as “most important” were general use of health data, types of data, and ethical issues in big data. All identified topics were incorporated into the final BD4P curriculum and workshops.

To reach an even broader audience and gather more comprehensive data, BD4P also hosted webinars; the first was in September 2015 and provided an overview of the program and discussed the needs assessment. Another webinar was held in August 2016 to provide information on the program, details on the training workshop, and information on how to apply to the training.

Similarly, public stakeholder meetings were held in December 2015 and June 2016 where input was received on the draft curriculum. Stakeholders, including representatives from academia, government, industry, and patient advocacy organizations, participated in this interactive working session. This input was essential in shaping the format of the original BD4P program and identifying prioritization of content development.

However, one of the most important ways that stakeholders shaped the BD4P program was through participation in the training workshops. Evaluations and feedback from these trainings were utilized in the development of best practices and each workshop iteration. Training materials, course curriculum, teaching methods, and key topics were revised based on participant feedback. Stakeholder engagement helped to ensure that the final curriculum and BD4P training course was appropriate and useful for patient advocates.

## Program Advisers

### Steering Committee

#### Academic

- ❖ C. Daniel Mullins, PhD – University of Maryland

#### Pharmaceutical Industry

- ❖ Joel Beetsch, PhD – Celgene Corporation

#### Technology

- ❖ Ariel Bourla, MD, PhD – Flatiron Health [*replaced Amy Abernethy, MD, PhD – Flatiron Health*]

#### Advocacy

- ❖ Meryl Bloomrosen, MBI, MBA – Patient Advocate
- ❖ Jennifer King, PhD – Lung Cancer Alliance
- ❖ Jane Perlmutter, PhD, MBA – Gemini Group [*replaced Bray Patrick-Lake – CTTI*]
- ❖ William Vaughan – Consumers United for Evidence-Based Healthcare Steering Committee

#### At Large

- ❖ Sally Okun, RN, MMHS – PatientsLikeMe
- ❖ Brad Smith, PhD – FasterCures

#### Appointed

- ❖ Beth Fritsch, RPh, MBA – FDA Office of Health and Constituent Affairs
- ❖ Claudia Grossmann, PhD – PCORI [*replaced Rachael Fleurence, PhD – PCORI*]

The BD4P project was advised by a multi-stakeholder steering committee providing strategic guidance and oversight. Nominations for this advisory group were taken via an open process in fall 2015 with individuals selected to fill each sector seats along with two appointed advisers from PCORI and FDA (the NIH representative was never appointed).

The steering committee worked with project staff and other advisers to ensure a focus on the long-term vision of the project and its deliverables. They assisted in reviewing and approving the BD4P program development and implementation plan, providing input on the BD4P program curriculum, and serving as instructors at the workshops. During the early phases they were tasked with engaging stakeholders and working with project staff to outline and recommend people for necessary program workgroups and/or subcommittees. Committee members provided recommendations for advisers, consultants, and SMEs to aid in program development, and also gave input on the long-term sustainability plan.

### Content advisers

The primary training curriculum and workshop format was designed by a team of education and instructional design experts from the University of Maryland, led by Stephen Roth, PhD, Associate Dean in the UMD School of Public Health. Dr. Roth and his team used input and resources from content advisers and SMEs to design the first training course. Curriculum topics were identified through the stakeholder needs assessment, and steering committee members and content SMEs provided the substance of the curriculum.

Many of these experts were part of the content workgroup, which reviewed and provided feedback on the initial curriculum and crucial issues. This workgroup was made up of experts in the areas of biostatistics, biomedical informatics, data science, health policy, and statistics, among others, and

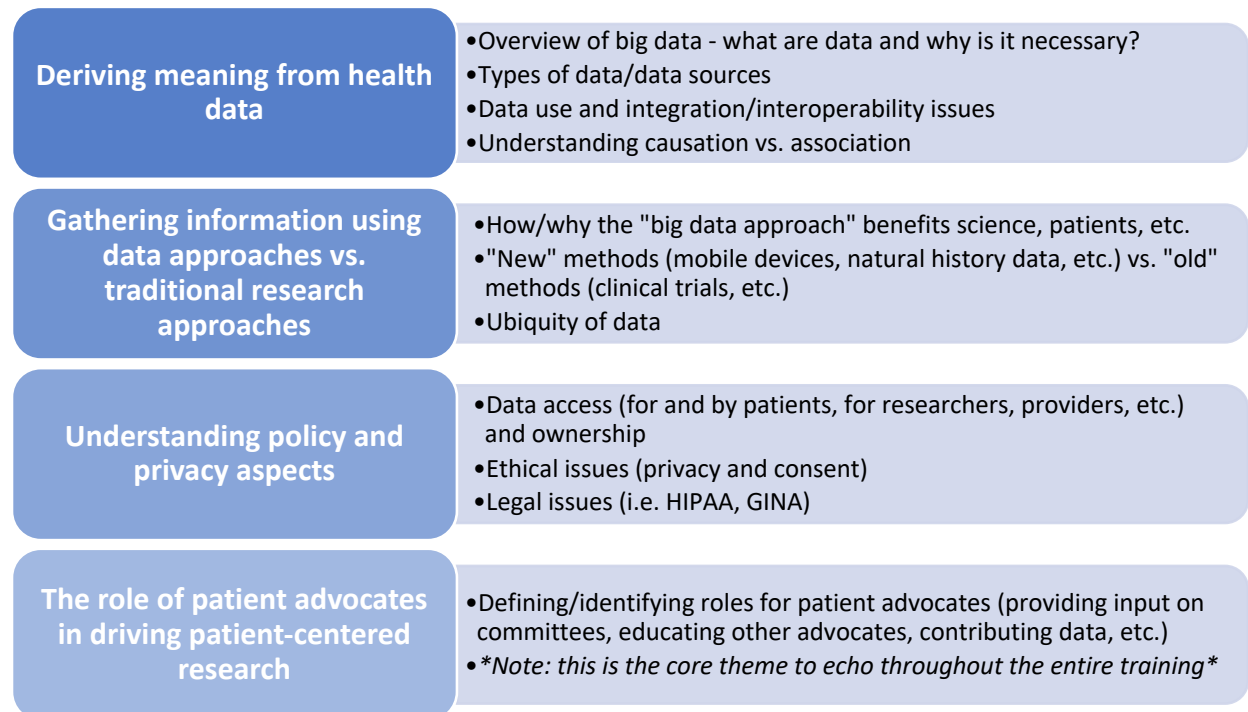
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members were recommended by the steering committee. The workgroup also included patient advocate representatives to ensure that the curriculum was focused on and suitable for the target audience.

## DESIGN

### Curriculum & Format Development

Determining the development needs, identifying program advisers, and deciding the critical issues to include in the training course were vital first steps in the creation of BD4P. Consolidating guidance from the needs assessment, stakeholder feedback, discussions with advisers, and recommendations from the content workgroup, the initial curriculum was modeled after **four core thematic areas**:



Dr. Roth and his team used this framework, along with the curriculum from content advisers, to model the curriculum and training course. The training was meant to have didactic elements supplemented by experiential learning elements – activities, discussions, and personal reflection. The eight original modules were:

- I. **Introduction to Big Data and Data Science**
- II. **Big Data vs. Traditional Research Approaches**
- III. **Making Big Data Useable**
- IV. **Involving Diverse Stakeholders in Big Data**
- V. **Legal and Ethical Issues Associated with Big Data**
- VI. **Data Access and Ownership Issues Associated with Big Data**
- VII. **Resources for Patient Advocacy**
- VIII. **Community of Practice of Patient Advocates**

These modules were augmented by the inclusion of case studies.

### Case Studies

The curriculum focused on the basic concepts of big data, with case studies to help clarify the concepts in a real-world – and condition-relevant – context. The case studies helped to illustrate the priority topics and core thematic areas and could be modified for different target audiences.

Case studies did not solely focus on the background of the organization/project, but instead the big data work that was applicable to BD4P concepts and patient advocates. It was important that the selected case studies were not overly technical, but were substantial and relevant to issues presented in the curriculum and discussed during the workshop. Cases could not be too controversial or homogeneous and they needed to represent different sponsors (i.e. government, advocacy group, private industry) with different applications (i.e. healthcare management, genomic discovery, identifying best practices). In order to provide a truly thorough overview, instructors were representatives from the case study organizations/projects. Having direct representation helped ensure that the case could be fully explored and participants could get in-depth answers to questions during open discussion.

Stakeholders offered suggestions for case studies that would be of interest. Five case studies were chosen for the first training: PatientsLikeMe, Flatiron Health, PCORnet, FDA's Sentinel System, and 23andMe. Using participant feedback, the program team made changes to the format and topic of case studies in the second workshop. Stakeholder input was crucial in identifying interesting and applicable case studies. For each workshop case studies were modified to reflect the needs and focus of a specific target audience, or to showcase big data innovations and new methods of patient engagement.

## IMPLEMENTATION

### Training #1

The first BD4P workshop was held in October 2016 in Washington, DC. It was a 2 ½ day, fully in-person training hosted at the Kellogg Event Center at Gallaudet University. Attendance at the first training was capped at 20 attendees to optimize participant experience and encourage learning. The trainees were active advocates with varying levels of experience in big data. They were also diverse – advocates from 15 different states with numerous disease focuses, including cancer, asthma, allergies, multiple sclerosis, diabetes, mental health, gastrointestinal issues, epilepsy, Crohn's disease, heart disease, sickle cell disease, and health disparities. Program participants engaged in lecture, discussions, and activities around what big data is, how it is being used, and its impact on patients.

The first day of training was a half-day, while the second and third days were full days. The first day mainly consisted of background and introductory information – participants got to know each other and were introduced to the first case study. The second day involved more background information on the basics of big data, along with revisiting the first case study and introducing three new studies. The last day consisted mainly of a discussion on the legal, ethical, access, and advocacy issues of big data, along with the final case study. All in all, the first workshop included five distinct case studies and eight curriculum modules. Each module and case study had its own instructor, and Dr. Roth was present on the first and third day to serve as a workshop moderator.

The course also included a number of individual and small-group activities for the trainees to complete. Each trainee had a workbook that contained activity worksheets, along with referenced readings, background information on the case studies, and a glossary of terms.



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Breakfast and lunch were provided on the full days of training, and participants were on their own for dinner. There was no official networking opportunity (i.e. dinner or reception), although participants did network with each other on their own. Trainees were aware that this was the first workshop and their input on the curriculum, format, and workshop delivery was vital.

After the workshop, program advancement was organized into four phases: *Evaluation*, *Curriculum Revision*, *Planning/Development*, and *Implementation*.

- 1) **Evaluation** – receive feedback from training participants and instructors through surveys and discussions
- 2) **Curriculum Revision** – revise and/or reorganize the curriculum and training/delivery format based on feedback from evaluations
- 3) **Planning/Development** – keep existing BD4P community engaged, organize workgroups to provide input on future trainings, and coordinate future trainings (in-person, online, or hybrid)
- 4) **Implementation** – finalize program curriculum and training structure, hold subsequent workshop(s)

### Evaluation

BD4P project staff reiterated throughout the training that trainee input was essential. Program staff made observations during the workshop, and also engaged in individual and group discussions with trainees. Participants completed evaluations after each module to rate the effectiveness of the content and offer advice; a subsequent evaluation was also conducted three months after the October training.

Responses to the module evaluations were positive, with most participants stating that the training and modules provided relevant information on complicated subjects, beneficial to the advocate community. Trainees also noted that the content was useful to their understanding of the subject matter even if the examples and case studies did not directly apply to their own work and/or disease focus. Attendees reinforced that in-person workshops were important, as some of the most valuable periods of the training were the open discussions with other participants and the Q&A with the instructors/presenters.

Although the in-person workshop was considered essential, some attendees suggested the workshop be shortened. They also suggested reducing the number of individual activities and increasing the amount of time devoted to group activities and/or discussions throughout the course.

Instructors also completed a survey evaluation, noting that the trainees were engaged and participated throughout the instruction, and suggesting more time for interaction with the participants. The major takeaway from the instructor evaluations was that they wanted more input into the session development; instructors wanted to add curriculum slides and include their own examples. There were also suggestions to have fewer instructors who could commit to the entire workshop so that they could understand the flow of the workshop and have a more cohesive presentation. They also recommended more training for instructors on the structure of the lesson and how best to present the materials. Along with the evaluations, the program team had discussions with instructors to get one-on-one feedback.

### Three-month Evaluation

The University of Maryland consulting team also conducted a three-month, post-training evaluation for participants and instructors of the first BD4P workshop. This was meant to identify how trainees had utilized the information and skills they learned in the training and also provide any additional feedback

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after having time to absorb the materials. Advocates had the opportunity to notate which topics were the most valuable to their work, and which topics should be included and/or emphasized more in subsequent workshops.

### Lessons Learned

The BD4P program success depends on having a workable product useful to advancing the missions and work of organizations with an interest in engaging patients in big data initiatives. Because interest in and demand for patient input around big data will likely remain high, it is important to ensure that the program is as efficient as possible and can be used as new innovations and trends emerge. Information from the evaluations and discussions helped to identify areas where the workshop and curriculum were effective, and places to make modifications to strengthen the course. After the first training, this information was used to make changes to the second workshop.

The biggest takeaway from the evaluations was the importance of communications – allowing ample time for discussion between trainees and SMEs, providing opportunities for participants to network with each other, and engaging instructors early in the curriculum development process so that their main points could be conveyed. All of these elements were incorporated into the development and implementation of the second training.

Another primary recommendation was streamlining the training format to better focus on issues that matter most to advocates. While participants valued the in-person workshop, some suggested that it should be shortened. The program team, along with BD4P advisors, decided to utilize a “hybrid” training model that incorporated both in-person and online components and condense the in-person session for the second training to 1 ¾ days. Instruction on the background and existing landscape of big data would be reviewed by participants independently and then covered in an online webinar.

Reducing the number of case studies and instructors were suggested for streamlining future workshops. The program team and advisors agreed; the case studies for the second workshop were cut to three and the number of instructors were reduced and encouraged to remain for the entire workshop.

Trainees and instructors had other ideas incorporated into the second training, including:

- Tasking instructors with contributions to curriculum revision and slide updates
- Having a designated moderator who attends the entire workshop to provide consistency and time management
- Providing background and introductory information on trainees, instructors, and case studies to participants before the in-person session
- Developing an online resource page where program participants could access pre-work slides, resources, workshop information, and introductions to trainees and instructors
- Reducing the number of individual activities and increasing the amount of time devoted to group activities and discussion
- Incorporating hands-on group activities, i.e. “how to design your own big data project”
- Including copies of slides in the participant manual
- Moving the workshop to a more centralized location with better transportation and restaurants
- Conducting the evaluations shortly after the course (rather than after each module) to keep the session flowing and to allow participants time to develop thoughtful responses

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A curriculum and workshop modification subcommittee of the steering committee was developed to assist program staff make these changes. These subcommittee members volunteered to serve as instructors for the second workshop. Additionally, SMEs in data science and legal issues volunteered to serve as instructors and help revise the curriculum for their areas of focus.

### Training #2

The second BD4P in-person training workshop was held in April 2017 at the Powell Tate Event Center in Washington, DC, incorporating recommended changes. The class size was reduced from 20 participants to 15. Multiple disease states were represented, including Duchenne Muscular Dystrophy, Parkinson's disease, and hemophilia, but the majority of participants were cancer advocates. Overall, the second workshop and the modifications made from the first version were well-received, including the addition of a networking dinner on the first night of training. The advocacy-focused curriculum modules also changed slightly for this course:

- I. Introduction to Big Data and Data Science**
- II. Big Data vs. Traditional Research Approaches**
- III. Making Big Data Useable**
- IV. Advocates & Other Big Data Stakeholders**
- V. Legal and Ethical Issues Associated with Big Data**
- VI. Data Access and Ownership Issues Associated with Big Data**
- VII. Improving Your Advocacy Skills to Impact Big Data**

In the hybrid format of this second training, participants engaged in one week of independent study “pre-work”, two webinars, and a 1 ¾ day in-person workshop. An introductory webinar was held to greet the participants, introduce some of the project team, answer preliminary questions, and explain the process and purpose of the independent study. This was led by the two members of the BD4P program team. Participants then had a week to review the background materials and resources for modules one through three independently before joining a second webinar for discussions, Q&A, and the introduction of the first case study. This webinar was led by a data science SME who helped refine the module slides and a representative from the case study organization.

One week later participants from across the country met for the in-person session. During the pre-work and workshop, an online resource page on the Foundation's website displayed the modules, resources (i.e. links to websites for review, case study background information), and recommended readings to supplement the curriculum materials. Presenting modules one through three independently made it imperative that the materials were thorough and easily understandable.

The smaller number of case studies allowed for more in-depth review of the featured studies and more time to discuss the application of concepts. The three case studies that were used during the second workshop (Google Health Analytics, the *All of Us* Research Program, and “Patient Engagement in Data Sharing”) were chosen because they represented multiple curriculum topics. Presenters for each case study were affiliated with the organizations, so they were able to answer questions during the open discussion and provide a comprehensive overview.

### Evaluation & Lessons Learned

Fewer instructors supported a more collaborative workshop. Because the instructors were involved with revising the curriculum and slides, they had a deep understanding of the content and were able to connect the topics with examples and references. Also, a smaller number of instructors and a single moderator who attended the entire workshop provided cohesion to the training.

Instead of focusing on individual activities, there was a concentration on group discussion and open debate. The program team also incorporated a large group exercise on the last day, focused on applying learnings. This tied together all of the theories and encouraged participations to think about developing their own project. It also encouraged communication among the trainees about the work they were doing, and how the information learned could be relevant to their efforts.

As recommended by participants from the first workshop, an evaluation was conducted a few days after the full workshop instead of after each module. Trainees were sent an online, anonymous survey to fill out and return within the designated time allotted. The majority of trainees responded to the survey, and the responses about the full training and the workshop modifications were very positive. They did provide suggestions for improving the workshop moving forward, and many of these ideas are incorporated into the “best practices” and recommendations for future workshops.

Responses showed that trainees liked the updated workshop format. One of the reasons stated was that the hybrid model ensured trainees were near the same level of basic understanding prior to meeting in person. Feedback from the first workshop showed a split: some trainees felt that they already had a grasp on those concepts and the time could have been better spent elsewhere, while some felt that more instruction time was needed than allowed for in the first workshop. For the second workshop, participants who were less familiar with the concepts were able to review the material in greater depth than those who felt that they already understood the majority of background information.

The majority of respondents thought that the modules presented during pre-work were appropriate; the only suggestions were to add more time for module review at the in-person session and including topics of integration and interoperability in the in-person session. The independent study, combined with the review webinar, enabled the training to focus on new concepts rather than spend time teaching material that many trainees already understood.

Providing participant and instructor biography slides during the pre-work also helped to get the workshop started quickly and efficiently. During the first workshop, the introductions took a lot of time and caused the instruction to begin late, creating a domino effect where each module was running past its scheduled time. Participants noted the rushed feeling in the evaluations and were concerned that some elements could have been skipped over. Allowing the trainees to “meet” each other virtually before meeting in person helped to keep the class on schedule and provided a forum for every participant and instructor to share their experiences and hopes for the workshop.

Trainees noted that they liked the case studies that were presented in the second training. The program team felt that reducing the number of case studies allowed instructors to focus on the training objectives. Similarly, providing trainees with the case study background information in the pre-work meant that the instruction could be spent on the application of the case and how it was relevant to BD4P participants. Also positively noted was the inclusion of the resources (background information,

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etc.) on an accessible webpage that they could review and reread at their own pace. Respondents thought that the materials were clear and helpful to their understanding of big data and good for introducing the concepts of big data.

Discourse and conversation around different viewpoints and ideas were encouraged, so the idea of a fully online program in lieu of the hybrid model was overwhelmingly rejected. Participants remarked that the hybrid model was ideal because it allowed for personal interaction, networking with other advocates and instructors, opportunities to ask questions and participate in discussions and exchange information. Participants also noted that the pre-work period allowed them to be better prepared to participate in discussion because they had a solid background on the subject matter.

Perhaps because of the perceived benefits of in-person training, trainees responded that increasing the amount of time for the face-to-face session would be worthwhile. The majority of respondents suggested that two days would be ideal – long enough for discussion but short enough time to accommodate home and work commitments. Trainees suggested that this increased time could be used to strategize current and future projects, identify how they can apply the BD4P training to their own work, and to network/collaborate with other advocates and presenters.

## ASSESSING THE PROGRAM

BD4P was developed *for* patient advocates *by* patient advocates. Development was an open process and the program staff relied on input from patients, advocates, data SMEs, and other advisers. Public meetings, webinars, calls for input, and one-on-one discussions gathered feedback from a diverse array of stakeholders. Their input helped to shape the curriculum, the workshop format, and the recommendations on program growth and expansion.

Advisers were consulted for their feedback and recommendations for future workshops and program continuance. Discussions with program advisers and stakeholders who attended both workshops concluded that the modified format worked well, the reduced number of presenters and the inclusion of a moderator helped the workshop flow, and the participants were eager to engage in the group discussions and embrace the collaborative dynamic.

The Foundation will no longer host the BD4P program. Project resources, along with best practices and a prototype for subsequent workshops (including information slides, case study outlines, agendas, suggested workshop formats, etc.), will be publically available on the BD4P page on the Foundation's website. The hope is that these materials can serve as a framework for developing future BD4P trainings for patients, advocates, and other interested constituencies. BD4P has the potential to reach many other audiences, including specific patient groups, clinicians, health providers, and others interested in big data in biomedicine.

### Program Growth & Expansion

Keeping in mind that no one with an interest in the subject matter should be precluded from learning about big data in healthcare, BD4P could be modified to more adequately address other audiences, such as clinicians, researchers, or other health providers.

New issues will emerge in both big data and advocacy, and the BD4P curriculum and case studies will need to be revised as necessary. Similarly, the course format may need modifications to satisfy trainee

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feedback or specific population needs. Thought leaders, SMEs, and patients will need to be involved in this process.

Personnel will be necessary to ensure continued day-to-day operations of the program, as well as any essential updates to the content and/or format. The program requires continuous management of intellectual concerns, but also routine tasks including communications, funding, and event planning. A more robust online presence that includes a website for trainees to engage in discussions and network with other advocates would be useful; participation opportunities could be posted so that advocates could apply their training and stay active after the in-person workshops.

BD4P has been received positively by the advocacy community, with the perception that it is timely and useful to their work. The framework has been developed and the program has the potential to continue to grow around a variety of focuses and new innovations. The interest in PCOR and focus on big data in healthcare drives the need for a population of engaged and educated patient advocates who can contribute to advancing research. The development and implementation of the BD4P project shows the importance of incorporating educated patient input into the development of new programs and enterprises.

*Note: this document was sourced through discussions with program advisers the utilization of existing BD4P documents, including project reports, proposals, curriculum slides, and white papers.*