

**BIG DATA SCIENTIST TRAINING ENCHANCEMENT PROGRAM (BD-STEP):
TO PROVIDE TRAINING AND RESEARCH OPPORTUNITIES TO ENHANCE
CANCER CARE AND TREATMENT**

1. PURPOSE

a. Program Announcement. The purpose of this program announcement is to provide information, policies, and application procedures to Department of Veterans Affairs (VA) facilities interested in providing a training and research program for data science fellows to gain experience within an oncology learning healthcare system environment. There are notable program element changes from the current Big Data Scientist Training Enhancement Program (BD-STEP). Therefore, currently selected and funded BD-STEP sites interested in continuing to participate will be required to submit a new application. Sixteen funded fellowship positions have been allocated to this program, to be distributed across the sites selected for participation upon approval from the BD-STEP Coordinating Center with guidance from the Steering Committee. Selected BD-STEP sites may also elect to have non-VA-funded fellows participate in this program in a without compensation status. Regardless of the fellow's funding mechanism, all designated BD-STEP fellows will be held to the same program expectations and will hereto forth be referred to in general as BD-STEP fellows. A notable change in the BD-STEP program for the current program announcement extends the program from a one-year base curriculum to a two-year base curriculum.

Recognizing the rapid increase of data generated in the clinical setting and its potential to impact patient care, this program seeks to leverage the VA data systems to support clinically-relevant, year-long training and research opportunities for early career physical scientists and engineers, in collaboration with VA clinician scientists. The goal of the program is to train a new cadre of scientists and engineers that has the skill sets to manipulate and analyze large-scale, multi-element patient data sets and to develop new algorithms and models complementing existing methodologies in patient-centered outcomes research. The desired objective of BD-STEP is to bring in new perspectives to analyzing the abundance of data available within VA to ultimately make a substantial difference and improvement in the quality of healthcare we provide our Veterans. With continued advancements in biomedical technologies (genomics, proteomics, nanotechnologies, targeted imaging, etc.) and the resultant rapidly increasing body of clinical data, administration of true "patient-centered care" will critically depend on the ability to harness myriad clinical information. In the long-term, enhanced utilization and application of VA data systems may result in fewer outpatient visits to the hospital, faster decisions for changing therapy, fewer hospitalizations, and improved, cost-effective health outcomes. BD-STEP is designed to bring the expertise of highly skilled data scientists-in-training to provide evidence-based determination of required large-scale system changes in clinical care needed to expeditiously improve patient outcomes. In addition to individual research projects, fellows will spend a portion of their time working on cross-site, operationally impactful projects that are of direct value and impact to the patient and the health care system. The focus of the cross-site operational collaborative project(s) will be determined by the BD-STEP Coordinating Center

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based on VA national priorities and clinically relevant priorities recommended by the National Cancer Institute (NCI).

There are opportunities within an integrated system like the VA to reuse clinical data to provide evidence based insights to improve clinical care while also resulting in significant cost savings. Specifically, in oncology where molecular testing is increasingly becoming a more important component of defining a patient's treatment plan, it is important to understand how to harness this information to improve health outcomes without at the same time causing a great deal of unnecessary harm through overtreatment.

BD-STEP challenges VA to move from the traditional healthcare model of observe and treat to a desired future state of predict and prevent. BD-STEP operates within the translational care program VA is building to leverage big data resources (e.g., clinical, genomics, imaging) in an adaptive learning healthcare system capable of responding to the rapid innovations of 21st century medicine.

Approved sites will provide graduate level training in clinical, health services and/or bioinformatics research for fellows who have demonstrated experience in bioinformatics, modeling, and management of large data sets. Each site will provide an overview of how they understand and apply big data in their clinical research setting, including the ethical and legal implications; an introduction to how data are generated in the course of clinical care; and how those data are aggregated at local, regional, and national levels. Sites will support BD-STEP fellows in leading a research project involving such data. Sites able to demonstrate experience incorporating molecular data into their clinical and research activities will be evaluated favorably.

Recruitment of early career physical scientist and engineering fellows having earned a PhD from accredited programs in relevant disciplines (to include engineering, chemistry, computer science, mathematics, and physics) will be the responsibility of the selected sites, with marketing assistance from the NCI's Center for Strategic Initiatives (CSSI). The BD-STEP Steering Committee, comprised of representatives from across VHA Offices of Research and Development and Academic Affiliations and the NCI will provide final endorsement of the fellows.

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b. Eligibility to Apply.

Applications may be made by VA facilities with expertise in 1) clinical research in oncology and/or hematology, with a list of current active IRB protocols, 2) big data, bioinformatics, or health services research with a demonstrated commitment to provide advanced training to early career scientists and engineers, 3) oncology service leadership committed to providing fellows with baseline clinical exposure to enhance their understanding of the healthcare delivery system and how it impacts their work, 4) demonstrated experience in leveraging data analytics to be applied directly to improving and impacting the patient care experience and outcomes, and 5) onboarding fellows in a timely manner to meet the program requirements of a one year fellowship to begin and end in alignment with the fiscal year calendar. Experience with managing and working with molecular data is a plus. Appropriate infrastructure and local leadership support for the initiative, as well as the commitment of both a clinician and a researcher to serve as program directors must be established at the time of application. No more than 2 applications may be submitted per VA facility, with each application proposing no more than 3 fellows engaged per application.

VA facilities must be willing to actively participate and commit to the national requirements of this program through attendance at monthly meetings, timely submission of national program requirements, and demonstrate previous success collaborating with local academic affiliates, and interest in establishing new relationships with local academic partners to successfully recruit and train fellows. Demonstration of previous success with and understanding of the importance to collaborate with VA sites on research and clinical work will be viewed favorably. Additionally, applications that demonstrate diversity in terms of uniqueness to VA (e.g. small facilities serving rural Veteran populations) and those that describe robust inclusion of culturally diverse faculty and opportunities for fellowship recruitment are highly encouraged.

2. BACKGROUND

Recent technological advances have been made to automate clinical standards of care, affecting the way providers deliver care to patients. However, it is important to understand that while current man-made machine interfaces may be the tool we use to predict the best course of care, human intervention is necessary to provide context and to avoid inappropriately treating patients due to a prescribed “one size fits all” care model. Our current set of informatics tools is able to present providers with infinite possibilities for treatment. When conceptualizing how to administer true “patient-centered care” we need to focus on harnessing the clinical information and data to actually improve health outcomes.

To address these future challenges and to better understand how to administer a “patient-centered” approach to delivering healthcare, VA medical centers (VAMCs) with interest in developing the infrastructure to educate and train providers, researchers and the next generation of data scientists on utilization of the VA databases and systems has been established through BD-STEP.

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In alignment with the goals of the program, NIH recognizes the need to build workforce capacity in quantitative sciences to better advance knowledge from myriad clinical and research data. Within the NIH, NCI's Center for Strategic Scientific Initiatives (CSSI) has partnered with VHA for BD-STEP. CSSI has as its mission the creation and unique implementation of exploratory programs focused on the development and integration of advanced technologies, trans-disciplinary approaches, infrastructures, and standards to accelerate the creation of data, knowledge, and tools to empower the entire cancer research continuum for patient benefits. The Center has historically initiated trans-disciplinary programs supporting the application of technologies and physical science approaches to clinically-relevant research, with emphasis on supporting the development of fellows. CSSI is well-qualified to provide program input and to help with identifying fellows with the appropriate background needed for BD-STEP success.

It is crucial for a fundamental shift to occur in the current methodologies we use to define and administer patient care. Improvements in any organization are often discovered by new talent and fresh perspectives. The revision of this program's requirements will bring new expertise to the VA to help the organization advance clinical research efforts and improve patient-centered care initiatives by utilizing VA's big data infrastructure. Employing new approaches in the application of big data in the clinical space, and using technology to improve healthcare, is an emerging market for healthcare reform and one in which VA is interested in exploring further with NCI.

3. PROGRAM EXPECTATIONS

a. Program Structure. Sites approved for the BD-STEP program shall have a two year training curriculum; appropriate facility infrastructure; expertise in clinical oncology and/or hematology research (with active IRB protocols); expertise in big data/bioinformatics or health services research; dedicated clinician and research mentors; qualified, supportive senior leadership; engaged leadership in oncology committed to providing fellows exposure to the clinical and healthcare environment; and be dedicated and qualified to support fellows. Subject to VA information security procedures, data resources that will be made available to the site directors and fellows include data from the following sources: the Corporate Data Warehouse, cancer registry, and Precision Oncology Program.

(1) Curriculum.

- a. Kick-off meeting: The curriculum will begin with a program kick-off meeting in October facilitated by the BD-STEP Director. This mandatory kick-off meeting will provide an overview and orientation of program expectations and goals and allow for all fellows, clinician and research mentors, and program directors to meet.
- b. Local Experience: Each site shall develop a local experience for the fellow to include: an orientation to the VAMC; training in clinical data acquisition, access, and use, and the application of big data in the clinical setting, including ethical and legal considerations; exposure to the clinical setting of the fellow's research

focus area; and training in the use of VA database systems. Training sites shall provide a basic overview in the following areas with an opportunity to pursue more intensive training: clinical trial design, medical decision making, and medical informatics. Opportunities for clinical observation experiences are required. 80% of the fellow's time will be spent conducting research activities; 20% of the fellow's time will be spent in the operational clinical setting and working on an operational cohort project, to be determined by the BD-STEP Coordinating Center for each FY cohort. Each VAMC is unique and should employ their specific clinical and research expertise. It is expected that the local experience encourages interprofessional activity. The proposed curriculum must be included in the application.

- c. Fellow Project: The proposed curriculum should also ensure that each fellow engage in a minimum of one project suitable for publication in a peer-reviewed journal to further research in oncology/hematology, through big data/bioinformatics and/or health services approaches prior to the conclusion of their training. The specific focus of the research project will be determined collaboratively between the fellow, the VA clinician and research mentors (described below) and the fellow's academic advisor. Working under IRB-approved protocols and with the guidance of the VA mentors, fellows will apply quantitative techniques (including data management, analysis, and modeling approaches) to selected VA data sets to address clinical research problems. The BD-STEP Coordinating Center will work in coordination with the NCI to monitor the progress and impact of the fellows on collaborative research projects within their VA teams and the ability of the fellows to understand and apply appropriate clinical research guidelines to their VA research projects.
- d. National curriculum: In addition to the local curriculum, fellows will be supported by the national BD-STEP program to include educational content areas such as quality improvement methods, leadership skills, current literature, career development opportunities and other areas of significant interest to VHA for the fellows.

(2) Infrastructure. Sites must demonstrate continued commitment to foster a high-quality learning environment and collaborative fellow experience that touches on research, education, and clinical delivery. Sites must provide a dedicated workspace and computer, with necessary word processing and data analysis software, and address a plan for facilitating timely VA appointments and computer/database access for fellows and, as needed, their primary advisor from their academic institution.

(3) Recruitment. BD-STEP sites will be responsible for recruiting and proposing fellows from physical science and engineering disciplines (to include engineering, chemistry, computer science, mathematics, and physics) with experience in informatics and management of large data sets. NCI's CSSI will assist with recruitment activities. The BD-STEP Coordinating Center will manage the fellow application process and work with sites to select and rank fellow applications; the exact number of fellow appointments per sites will be recommended by the BD-STEP Coordinating Center and approved by the Chief Academic Affiliations Officer. NCI, the participating VA facilities, and the fellows and their VA mentors and academic advisors each have specific responsibilities for adhering to VA's rules for information security and privacy. Proposed fellows must comply with requirements to provide personal background information, undergo criminal and other background investigation, provide fingerprints, satisfy all VA requirements for suitability of employment, and must demonstrate completion of all VA-required training in research safety, information security, privacy and related topics.

(4) Funding. Funding for administrative support is contingent on pending ORD FY appropriations. Funding will be prioritized to sites with active BD-STEP fellows. Sites with only fellows on without compensation appointments may be eligible to receive administrative funding support and will be expected to support their fellow's participation in meeting the requirements of the program independent of funding. The funding must be utilized in an efficient, appropriate manner to support program administration, curriculum development and implementation, fellow recruitment, travel to BD-STEP-relevant meetings, and related research activities. Assistance in executing these funds can be found in "Appendix B: Additional Funding Support".

(5) Program Directors. Two program directors will be identified per site; one will serve as the research/administrative lead, and the other will serve as the clinician scientist mentor. Program directors must be VA paid employees who have demonstrated expertise in clinical and/or health services research, are experienced in administration of an academic program, and have demonstrated ability to effectively teach and mentor. The administrative/research program director must have a track record of expertise, leadership, scholarship, and mentoring in issues related to oncology and/or hematology, big data clinical and health services research, and healthcare improvement. Sites are allowed to have more than two directors as long as the previously stated requirements are met.

Designated clinician scientist mentors for the fellows must currently be practicing, have demonstrated expertise in clinical and/or health services research, be qualified to serve as a VA Principal Investigator for the proposed research, have active IRB protocols in oncology research, have demonstrated ability to effectively teach and mentor junior scientists, and have experience and interest in providing the fellows with baseline clinical exposure to enhance their knowledge of healthcare delivery. Mentors should have interest in advanced analytics/big data and be available to provide fellows with the exposure and training needed to understand the clinical environment.

If the program directors do not possess all of the above traits, the program must demonstrate that the fellow will be exposed to a mentoring team that addresses the multifaceted training needs for this training experience.

(6) Site Collaboration. Cross-site collaborations are encouraged and the BD-STEP national program office will assist with establishing such collaborations among the designated sites. Collaboration shall include such issues as curriculum development; implementation and improvement; program evaluation; and communication with all of the program directors at the various training sites. Program directors are expected to actively participate and help foster such collaborations among BD-STEP sites. All fellows will be expected to dedicate 20% of their time to understanding the clinical environment, working on local operational projects, and supporting BD-STEP cohort operationally-relevant project at the determination of the BD-STEP Coordinating Center.

(7) Academic Institution Collaboration. Program directors and Clinician Scientist mentors shall foster collaboration between the fellow's primary academic institution and the VA site. As fellows come from academic institutions, their academic advisors are expected to contribute to and collaborate on the training and research projects. To facilitate participation of the academic advisor, the program director shall encourage collaborative research and establish a regular meeting schedule. Additionally, as needed, program directors will facilitate the appointment of the academic advisor in a without compensation (WOC) appointment to the VAMC. The academic advisors will be informed of the requirement to provide information to VA and engage in required training in research safety, information security, and privacy in order to receive VA WOC appointments. If warranted by their level of participation, academic advisors should be included in authorship of conference presentations and peer-reviewed publications resulting from the training program projects.

b. Program Implementation. Program implementation expectations include the following:

(1) Fellows. Appointed Fellows are paid through VA's advanced fellowship program and shall spend approximately 80 percent of their time in VA training and research activities. The remaining 20 percent will be reserved for operational activities that are clinically relevant and impactful. All fellows are expected to participate in the BD-STEP kick-off and all events during the kickoff week, monthly BD-STEP seminar calls, monthly roundtable calls (including leading a roundtable presentation), end of year graduation program, and two face-to-face meetings to encourage collaboration and scientific and operational discussions amongst all fellows and sites. Fellows are also expected to provide quarterly and end of year progress reviews to the BD-STEP Coordinating Center.

(2) Without compensation (WOC) Fellows. WOC fellows will be approved through the BD-STEP Coordinating Center, but funded through mechanisms external to VA and appointed to the VA in a WOC designation. Fellows will spend approximately 80 percent of their time in VA training and research activities. The remaining 20 percent will be reserved for operational activities that are clinically relevant and impactful. All WOC fellows have the

same administrative requirements as VA-paid fellows and are expected to participate in the BD-STEP kick-off and all events during the kickoff week, monthly BD-STEP seminar calls, monthly roundtable calls (including leading a roundtable presentation), end of year graduation program, and two biannual face-to-face meeting to encourage collaboration and scientific and operational discussions amongst all fellows and sites. It is the responsibility of the fellows' VA site or academic institution to sponsor their travel to required events, and support the time needed to complete program requirements. Fellows are also expected to provide quarterly and end of year progress reviews to the BD-STEP Director.

(3) Program Directors. The two designated program directors are responsible for site-level leadership of the training program and its implementation, including helping to identify primary mentors and mentoring teams. One program director will serve as the research/administrative lead, and the other will serve as the clinician scientist mentor. The research/administrative lead will be responsible for all facets of the training program, including assignment and coordination of mentoring teams, reserving dedicated time for routine engagement with the fellow for mentoring sessions (with a minimum of quarterly formal reviews on training progress), engage the fellows in a clinical experience, evaluation of fellows and the site-level program, curriculum implementation, and all administrative issues (including fellow appointment, coordination with other BD-STEP sites, coordination with associated academic institutions, etc.). Both designated Program Directors will engage local VA leadership and the fellows' academic mentors (at a minimum) on a quarterly basis to review work being done by the fellows. This should include the VA executive leadership, the Associate Chief of Staff for Research and Development, and the Designated Education Officer. All program directors are required to actively participate in the kick-off meeting, monthly BD-STEP site director program calls, and end of year graduation to encourage collaboration across all sites. Program directors will ensure that appropriate processes are in place to arrange fellow travel to mandatory BD-STEP meetings. Additionally, Program Directors will also be responsible for ensuring all VA data use by fellows is in accordance with VA guidelines. Program directors will also be required to submit end of year reports on deadline and be responsive to any other national administrative program requests in a timely manner.

(4) Primary Mentor. Program Directors will provide assistance with clinical and health services research methodology and content related to the fellow's project(s), as well as guidance in personal and professional development. Program Directors will assign either themselves or determine an appropriate primary mentor for each fellow who will be expected to provide daily guidance during the fellow's initial orientation and introduction to the VA and to be readily accessible to fellows for guidance/assistance as needed throughout the training program. Following initial orientation, mentors will meet regularly (e.g. weekly) with fellows to assess their progress, serve as role models, and provide constructive feedback and assistance in meeting each fellow's goals. At the start of the training program, primary mentors will engage with the fellows to develop a training plan and are expected to initiate discussions on authorship for all research outcomes (such as presentations and publications) from the training program project.

(5) Additional Mentors / Mentoring Teams. Given the complexity of education planning for fellows, several mentors are often needed. To maintain collaborations with the fellow's primary academic institution, their academic advisor will continue to serve in an advisory capacity. Additional mentors may also be included as part of a larger mentoring team to address specific training needs (i.e. epidemiology, biostatistics, medical records, clinical specialty, etc.). These additional mentors may provide assistance with research methodology and content related to each fellow's project(s) or guidance in personal and professional development. Additional mentors differ from primary mentors in that they are not responsible for the overall coordination of the training program. These individuals are expected to meet regularly (e.g., weekly, biweekly, or monthly) with the fellows to assess their progress, serve as role models, and provide constructive feedback and assistance in meeting each fellow's goals through the fellows' learning plan. Mentors are expected to participate in formative and summative evaluation of fellows and the training program under the direction of the primary mentor and/or program director. Where specific expertise is needed, mentorship may come from mentors at other VA institutions, individuals from VA program offices, faculty from academic affiliates, individuals from offices within the NIH, or private sector partners. BD-STEP sites should be willing to participate in such collaborative cross-institution/agency and private sector mentorship where feasible.

(6) Recruitment. Each site may appoint two VA-paid fellows each academic year, with the expectation that each fellow will have a 2 year experience. Programs may request approval for a third year for fellows with exceptional accomplishments in order to complete research projects that make substantial contributions to the VA. Primary recruitment activities are the responsibilities of the designated BD-STEP sites. The BD-STEP national program office, in coordination with the NCI, will also be available to assist with convening informational sessions with each of the BD-STEP site locations and local academic institutions in an ongoing recruitment effort to solicit fellow applications. NCI's CSSI will assist with recruitment by helping to identify relevant contacts and academic leads and local institutions. Sites should develop a plan for recruitment upon initial application and continually revise the plan in preparation for each fellow cohort. Instructions for requesting 3rd year extensions are posted on the Advanced Fellowships website.

(7) Research Project. All fellows will participate in at least one substantial research or healthcare improvement project, suitable for publication in a peer-reviewed journal, to which they make a substantive, independent, and identifiable contribution. The project should leverage VA data systems and represent a new direction in furthering cancer research, not an incremental continuation of current research at the VA site. The topic of the project should be relevant to improving Veteran's health, although VA medical facilities do not necessarily have to be the sole sites of the research. The projects should be identified and selected collaboratively by the clinician scientist mentors, fellows, and the academic advisor from the fellow's primary academic institution. Fellows are encouraged to work with local, regional, or national leaders to define how their project relates to health system goals, outcomes, or quality measures.

(8) Operational Project. All fellows will participate in one cross-site collaborative and operationally impactful project during the program that is of direct value and impact to the patient and health care system. Fellows should also participate in projects involving interprofessional improvement efforts whenever available. It is expected that at least one of these efforts will be a significant and impactful project to which the fellow makes a substantive, independent, and identifiable contribution. The topic of the projects should be of direct relevance to VHA's mission and/or operations. VHA medical facilities do not necessarily have to be the sole target for project activities which may also include operational partners at the regional or national level. Successful completion of a significant project includes written description of the project and its results (preferably including submission for publication or other formal dissemination efforts) and presentation of the project to policy makers and stakeholders and/or at a regional or national professional conference. The focus of the cross-site operational collaborative project(s) will be determined by the BD-STEP Coordinating Center based on identified national VA clinical priorities and clinically relevant priorities recommended by the NCI. The identified project will support providing the foundation for VHA to begin building a learning healthcare system in oncology.

(9) BD-STEP Kick-off Meeting. At the beginning of each year of the training program, fellows, program directors, VA clinician scientist mentors, and academic primary investigators will convene for a kick-off meeting to launch the program. Program expectations, project proposals, and a VA overview will be provided during this program, with guest speakers invited to present on topics such as the future application of big data in the advancement of clinical care outcomes and how fellows can best prepare for the next steps in their careers. The goal of this meeting is to establish the BD-STEP community and to introduce the fellows to national program office resources (i.e. CDW, VINCI, ViREC, and QUERI) to help overcome barriers/hurdles encountered during the duration of the program. Sites will be required to present briefly on their leadership, ongoing projects, and unique strengths/resources. This meeting will be co-sponsored and coordinated with the NCI's CSSI.

(10) Annual BD-STEP Face-to-Face Meeting. To encourage cross-site collaborations and to build the network of BD-STEP fellows, a meeting will be held during the course of the year to provide an opportunity for the BD-STEP community to meet face-to-face in coordination with a major industry-relevant conference that fellows will attend. Fellows are required to attend and BD-STEP site leadership, mentors, and academic advisors are welcome to attend. This meeting will be co-sponsored and coordinated with the NCI's CSSI. Willingness to approve and support official travel for this meeting is expected, so long as consistent with VA travel policies at the time.

(11) BD-STEP Graduation. At the conclusion of the training program, fellows, program directors, and VA mentors will convene to present outcomes to date, next career steps, training recommendations, and barriers/hurdles encountered. The goal of the meeting will be to share successful training and implementation strategies and identify areas for new

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collaboration and coordination among sites. This meeting will be co-sponsored and coordinated with the NCI's CSSI.

c. Program Changes and Requirements for Continued Participation.

OAA must be notified of significant changes to fellowship program, including issues such as change in leadership, insufficient funding, or any other reason why the approved proposal is not being implemented as planned. Sites that do not execute the program as described in this announcement are subject to remediation and potentially to loss of site approval.

d. Post-program follow-up and tracking. The BD-STEP Coordinating Center will work with all sites and fellows to monitor the results of an assessment of fellows' satisfaction with the program, increased understanding of healthcare delivery, their future employment, recruitment to VA, success in publishing in peer-reviewed journals to further patient-centered outcomes research, awards, and continued collaborative work in the field of big data clinical and health services research. Such tracking information will be considered in evaluation of participating sites at the time of future program re-competition. Although no previous tracking information is required, sites are encouraged to provide information on previous trainees' success from their programs, to include publication, employment, and award data.

4. POLICIES

a. Governance. The Office of Research and Development (ORD) in collaboration with the Office of Academic Affiliations (OAA) maintains responsibility for the administration of BD-STEP. The BD-STEP Coordinating Center will work with ORD, OAA, and the NCI to carry out the practical implementation of the program and provide scientific and administrative oversight. The BD-STEP Steering Committee will serve as an advisory body for BD-STEP and is comprised of members from OAA, ORD, the NCI, and other experts from relevant program offices across the VA (i.e. ethics, patient care services, pharmacy, etc.) as well as external institutions. The BD-STEP Steering Committee will provide expertise and strategic guidance for the program. This program is a collaborative effort with the NCI. This program is subject to Handbook 1400.07, Education of Advanced Fellows.

b. Program approval. The training sites will be approved until re-competition is announced by OAA. VHA's BD-STEP Coordinating Center in coordination with OAA and the NCI's CSSI will monitor program implementation. Approval may be withdrawn from sites that have been unable to complete fellows' VA appointments within 2 months after fellows have been matched to VA sites. Approval will be withdrawn from sites that are identified to no longer possess the capacity to provide a high-quality training program, actively participate in the community calls, or kick-off and annual meetings. After sites miss two sequential BD-STEP meetings without an excused absence (such as a mandatory event at the VAMC), they will be required to provide a plan to improve attendance or delineate a designee to attend. The plan will be submitted for approval by the BD-STEP Coordinating Center. Should a site's participation be terminated, fellows participating at that site will be allowed to complete the program at another participating site, if a suitable alternative can be identified.

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c. Fellow Nomination Criteria. BD-STEP sites, with the final approval from the Chief, Office of Academic Affiliations, will have the responsibility for fellow identification and proposed recommendation for selection by the BD-STEP Coordinating Center.

The program seeks early career physical scientists and engineers (fellows) from NIH-supported institutions to participate in collaborative training and research experiences at selected VAMC BD-STEP sites. Fellows from physical science disciplines (to include engineering, chemistry, computer science, mathematics, and physics) with experience in bioinformatics, modeling, and management of large data sets will be considered.

Prior to participation in this program, prospective fellows shall:

- (1) Have earned a PhD* in a physical science, engineering, or related discipline (to include chemistry, physics, engineering disciplines, computer science, and mathematics) from an accredited program. To be eligible, all applicants must have received their terminal degree within the previous 5 years at the time of application.
- (2) Have experience in bioinformatics, modeling, and management of large data sets; strong background in advanced mathematics and statistics; and proficiency in at least one programming language. Experience with managing and working with molecular data is a plus.
- (3) Have support of his/her academic advisor to participate with plans to continue collaboration between their university and BD-STEP responsibilities. The academic advisor should express commitment to engage in regular meetings with the fellow and VA site directors focused on research projects and fellow career development.

*Post-doctoral fellows meeting all above requirements and interested in participating in this program on a without compensation (WOC) appointment are encouraged to apply. WOC-appointed fellows will still receive the designation of being a BD-STEP fellow and be expected to complete all program requirements.

d. Fellow Appointment and Compensation

- (a) Appointment authority. Appointments will be made under 38 U.S.C. 7405 (a) (1) (D)
 - (1) Fellows are eligible for health and life insurance benefits.
 - (2) PAID Codes. The PAID codes will be provided in the memoranda notifying facilities of their selection as a fellowship site. Appointments will be terminated at the end of the specified training period.
- (b) Stipend. Stipend rates will be determined by OAA, depending on the discipline and previous education of the fellow. Current rates are listed on the OAA intranet web site at

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<http://vaww.va.gov/oa> (then “OAA Support Center”, then “Facility Locality Based Per Annum Stipend Rates”). OAA reserves the right to use a different mechanism to determine fellow pay. For more information about health disciplines not listed in the table, contact OAA.

(c) Stipend Supplementation. Fellows shall not receive additional revenue from any source in compensation for their duties in this program. Questions about non-VA, pay, dual compensation, potential conflict of interest, can be definitively addressed by local Regional Counsel or General Counsel.

(d) Participant Eligibility

- 1) At least a doctoral degree (PhD) in a physical science, engineering, or related discipline (to include chemistry, physics, engineering disciplines, computer science, and mathematics) from an accredited program.
- 2) Meet all eligibility criteria for hire within a VA facility.
- 3) Be a U.S. citizen.

(e) Educational Detail. Fellows may be detailed to other educational institutions without loss of pay, but under no circumstances may the total time spent in non-VA institutions exceed one sixth of the total hours a fellow is in a pay and training status with VA. Should a program wish to have fellows conduct activities at non-VA sites, an appropriate affiliation agreement must be completed and prior written approval from Office of Academic Affiliations must be obtained.

e. VACO Support.

(1) ORD support. Pending FY appropriations, ORD will distribute \$20,000 to each competitively-selected BD-STEP site (Boston, Durham, Houston, Palo Alto) to support program administration, curriculum development and implementation, fellow recruitment, travel to annual BD-STEP meetings, and research activities. Additionally, the BD-STEP Coordinating Center will determine on an annual basis, additional funding support for each VA-paid fellow (not to exceed \$10,000 per paid fellow) to support their development. Each site will have an opportunity to request additional funding to support specific BD-STEP initiatives and/or collaborative efforts with other sites, to be submitted to the BD-STEP Coordinating Center for funding consideration no later than March 1, 2020. The actual amount of funding is subject to change based on ORD budgetary constraints as well as the changing funding needs of sites.

(2) Other VACO support. Overall programmatic administration at VACO will be administered by the BD-STEP Coordinating Center. Standardized national curriculum will be developed and shared with sites at the beginning of the year; just-in-time curriculum modules will be developed and shared throughout the year, for sites to support their fellows' participation in.

f. Liability. Fellows will be protected from personal liability while providing professional services as a fellow at a VA facility under the Federal Employees Liability Reform and Tort

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Compensation Act, 28 U.S.C. 2679(b)-(d). Should a program wish to have fellows conduct activities at non-VA sites, prior written approval from OAA must be obtained.

g. Expenses. Except as detailed above, expenses connected to the fellows' recruitment are not funded under this program. Transportation to the VA facility and housing arrangements are the sole responsibility of the selected fellows.

h. Service Obligation. There is no service obligation after completion of the training program. However, fellows are encouraged to seek VA employment upon training program completion.

i. Identification of Fellow Status.

(1) Fellows shall notify VHA's Office of Research Development (ORD) as required of any publication or presentation using procedures for electronic notification **through the ORD PubTracker Website: <http://vaww.pubtracker.research.va.gov>.**

(2) Fellows shall also identify their VA affiliation in all reports and presentations during the training program and after the training program if the report or presentation is related to activities conducted during the training program. Failure to do so will result in the site not meeting program expectations and may jeopardize future participation in the program.

j. Individual Development Plan

The Program Directors will work with each fellow within the first 90 days of entering the program to develop an individual development plan that will help the fellow his/her learning and training objectives for the year. This plan will be developed as a collaborative effort with the VA Program Directors, primary/secondary mentoring teams, academic advisor, and the fellow. The plan shall address the fellow's BD-STEP program goals, long-term career goals and identify the local resources to be used. This plan shall be revisited periodically in order to serve as a meaningful dynamic document assisting in the fellow's development.

k. Site Commitment to National Program

Each site must be willing to participate in and substantially contribute to regular, nationally coordinated administrative meetings and conference calls. Each site will be required to support training elements of the program as directed by the BD-STEP director. In addition to the kick-off, graduation and annual BD-STEP meeting, each site must also be willing to participate in a substantial and ongoing way to the development and deployment of nationally coordinated training and educational activities to include regular teleconferences.

5. FACILITY ELIGIBILITY CRITERIA

The sponsoring VA facility must actively conduct research in clinical oncology and/or hematology, big data/bioinformatics, and health services and have documented success in collaborating with academic universities and understanding how to provide non-clinical fellows with the baseline exposure they need to better understand the healthcare environment.

Additionally, VA facilities must have the administrative structure and support in place to provide timely onboarding to their fellows.

6. SELECTION CRITERIA

a. Site Characteristics. The facility must provide evidence of committed leadership, time, and personnel to support a culture of excellence in big data clinical and health services research in oncology, healthcare improvement, education, clinical care, and administration. Sites must be committed to support fellows, program directors, and their clinician scientist mentors. Sites must continue to support the following criteria:

- (1) Facility commitment to build and sustain an outstanding learning environment.
- (2) Strong leadership by the program directors, clinician scientist and mentoring teams, and associated faculty – specifically with regards to clinical and health services research, and demonstrating an understanding of how to leverage big data to support the principles of an adaptive learning healthcare system.
- (3) Outstanding research in oncology and/or hematology. Interest in advanced analytics/big data and contributing to the program’s goal of creating a learning healthcare system environment for oncology.
- (4) Past experience providing high quality mentoring for early career scientists, including interprofessional educational opportunities clinical learning opportunities at the site.
- (5) Commitment and past expertise with recruiting research fellows and providing training at the VAMC.
- (6) Commitment to sponsor a fellow at the site, including the ability to accommodate the fellow with a work space, computer terminal, and other basic logistics.
- (7) Commitment to develop a comprehensive training curriculum covering the VA and its healthcare systems, best practices in use of clinical data, and use of VA database systems.
- (8) Commitment to develop individualized learning programs with fellows.
- (9) Evidence of a strong administrative infrastructure to support a fellow program, including evidence of successful and timely VA appointments and computer/database access for fellows. Demonstration of understanding how to access data in VA and/or an established agreement with the VINCI and CDW team will be viewed favorably.

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(10) Past experience supporting collaborations outside VHA, including collaborations with other government agencies, academic institutions, and private entities.

(11) Commitment to be an active participant in building a strong, cohesive nationwide training program and demonstration of past experience and success with VHA collaborations.

(12) Evidence of sound evaluation strategies for programmatic and individual evaluation.

(13) Willingness to approve and support official travel as described in this document for the fellows to attend at least one annual BD-STEP meeting, and for program directors and clinician scientist mentors to attend BD-STEP associated meetings, so long as consistent with VA travel policies at the time. Additional commitments for fellow and faculty travel to disseminate BD-Step work at national meetings, conferences, and other venues will be reviewed favorably. All travel commitments are contingent upon VA travel policies and regulations.

b. Site Applications. The facility must submit the information requested in Attachment A of this RFP.

7. REVIEW PROCESS

a. Review committee. An ad hoc, interprofessional review committee consisting of representatives from VHA, NIH, and an external health care partner with expertise in learning health care systems will review and assess each site’s application.

b. Scoring of Applications. Responses to this RFP must assert commitment to the goals of this program, and demonstration of ability to meet program requirements. Reviewers will consider each of the review criteria below in the determination of the merit of the training program, and give a separate score for each. These requirements include the following areas:

<p><u>Leadership</u> to build and sustain an outstanding learning environment; evidence of a strong administrative infrastructure, including facility and program director capabilities and commitments. Evidence of expertise in clinical oncology and/or hematology research and big data, bioinformatics and/or health services research. Demonstrated appreciation of and success with understanding how to bring research, operations and data into a collaborative space to support learning healthcare system activities. Applications demonstrating innovations in diversity (e.g. site, faculty, and fellow recruitment) are highly encouraged.</p>	<p>20 pts.</p>
<p><u>Curriculum</u> that describes program level learning objectives and instructional strategies for accomplishing those objectives (including the development of individual development plans for the fellows to achieve their learning/training goals for the year). Description of local level instruction and workplace learning activities proposed to accomplish the</p>	<p>20 pts.</p>

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<p>BD-STEP mission, including facets related to VAMC orientation (to include clinical exposure), clinical and health services research, VA database systems, and supporting the fellow’s time to contribute to an operationally relevant and impactful project to the program. Evidence of innovative approaches to collaborative learning in a healthcare environment. Share opportunities to contribute expertise and/or educational programming for the coordinated national BD-STEP. Training curriculum will be evaluated for whether it’s conducive to preparing fellows for successful careers as health care data scientists.</p>	
<p><u>Learning Environment</u> that has capacity to fulfill the proposed curriculum, including faculty mentorship, teaching ability, dedicated mentoring time, interprofessional collaboration, and other features necessary to facilitate training and research opportunities in big data clinical and health services research. Demonstrated success in providing clinical exposure to non-clinical staff to enhance their understanding of healthcare delivery and to provide fellows with the institutional support needed to ensure effective training outcomes. Demonstrated success in recruiting a diverse cadre of academic fellows to the VAMC for research and training activities (e.g. Recruitment Plan to Enhance Diversity). Sites will also demonstrate examples and evidence of success being a pioneer in advancing translational care activities for VHA to create a learning healthcare system for oncology.</p>	25 pts.
<p><u>Research Environment</u> that allows the fellows to be immersed in a robust VA environment engaging in research, clinical and education initiatives, policy, program evaluation, and implementation of clinically-relevant, projects and activities with potential for healthcare improvement. Demonstration that the fellows will be surrounded by faculty and staff role models demonstrating partnership/stakeholder focused clinical and big data, bioinformatics and/or health services research in oncology and/or hematology (through the availability of current active IRB protocols). Demonstration of research collaboration across VA, academic, and industry partners.</p>	20 pts.
<p><u>Evaluation Plans</u> for formative and summative evaluations for the program’s overall mission and the individual fellows’ accomplishments of their learning objectives.</p>	15 pts.
<p><u>TOTAL</u></p>	100 pts.

c. Selecting council. Final ranking may also take into account issues such as geographic distribution of approved sites and other OAA program awards to applying sites. The BD-STEP Coordinating Center will coordinate with the Steering Committee to review the BD-STEP site nominations and make recommendations to the Chief Academic Affiliations Officer who will make final determination.

8.

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9. CONTACT PERSONS

For information or questions related to the application process, please contact Kim Uhl by email at Kimberly.Uhl@va.gov or by phone at (562) 826-5996. For information or questions related to this announcement, please contact Frank Meng by email at Frank.Meng2@va.gov or Colleen Shannon at Colleen.Shannon@va.gov.

Appendix B: Additional Funding Support

1. Funding for administrative support from ORD will be prioritized for sites with active BD-STEP fellows.
 - a. The amount of funding is contingent upon ORD's annual budget. In the event that funding is not available or dramatically decreased, active sites are strongly encouraged to utilize their own budgets to support the development of the fellow as outlined in the BD-STEP Program Announcement.
 - b. The funds will be transferred from ORD to the BD-STEP site./
 - c. It will be the responsibility of the BD-STEP site director to monitor the arrival of the funds.
 - d. Per the BD-STEP Program Announcement, the funding must be used to support program administration, curriculum development and implementation, fellow recruitment, travel to BD-STEP-relevant meetings, and related research activities. It is required that each site provide support to allow fellow to attend at least two (2) annual meetings, as long as consistent with VA travel policies at that time.
 - e. The expenditure of funds will be tracked by the BD-STEP site. Sites should be prepared to provide information on the usage of the funds to the BD-STEP Coordinating Center upon request upon request.
 - f. Determination should be made at the mid-year funding report if funding cannot be properly utilized so that the BD-STEP Coordinating Center can assist in avoiding any loss of funds.