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CHAIRMAN, BOARD OF TRUSTEES

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National Heart, Lung, and Blood Institute
Office of Translational Alliances and Coordination
National Institutes of Health

RFI: NHLBI Translational Research
Notice #: NOT-HL-16-472

Dear Dr. Marek:

Thank you for the opportunity to provide comments to NHLBI on early translational research activities supported by the Institute. Initiatives to transform scientific and medical research into new jobs, products and businesses is one of the core areas SSTi strengthens to create a better future through science, technology, innovation and entrepreneurship. We are pleased to provide input on how NHLBI might further facilitate and accelerate the implementation of heart-, lung- and blood-related innovations.

As NHLBI understands well, the early translational research process is complex and uncertain. Three particular barriers to success are identification, development and scale. Identification is a barrier when investigators and their institutions do not identify an innovation's potential for translation. Development is a barrier when the innovation does not receive either the business- or technological-focused growth needed to succeed. Scale is a barrier when an innovation does not receive the executive talent or capital needed to transform into a new business or product. Fortunately, organizations throughout the country have identified models for alleviating these pain points in the process.

SSTi's university and laboratory partners report that investigator training programs can help to address identification. Programs like I-Corps are designed to equip a research team with the skills necessary to lead a resulting startup, helping to address development and to prepare for scale. Experience suggests that while lead investigators are less likely to leave their institutions to direct a spin-out, these programs are helping investigators recognize when an innovation has translation potential, lowering discovery costs for the institution. I-Corps is one model for this training, although the lean-focused business model embedded in I-Corps is shared by a wider array of entrepreneurial training programs that offer similar promise. Arrangements between NHLBI and the provider of a program delivering the customer-first approach to product development could improve identification, and perhaps have additional benefits, for the Institute.

Another means for NHLBI to address identification issues is to ensure it is making sufficient investments in the training and development of its own translational research staff. Many universities and labs do not make these investments and therefore miss opportunities to identify high-potential innovations or implement partnerships or programs that could yield greater success. Several industry associations, such as the Association of University Technology Managers (AUTM) and SSTi, offer opportunities for professional development and exposure to recommended and innovative practices, and a number of universities provide coursework and professional development specifically for tech commercialization.

NHLBI works with BioHealth Innovation in Maryland to place entrepreneurs-in-residence (EIRs) as a means of providing business expertise to investigators; an additional use of experienced entrepreneurs, and one that Georgia Research Alliance has had success with at universities, is to have EIRs work with the tech translation staff and investigators on reviewing discoveries for development potential. Another critical component of effective staff development is hiring practices — many labs have their institutional translational research knowledge tied to a small staff and lose all of it when turnover occurs.

NHLBI currently offers programs, including SMARTT, GTRP and PACT, helping address the technical side of development. Through additional partnerships and grant or contract services, NHLBI may be able to better leverage these existing programs, find solutions for innovations not covered by these programs, and address the market component of development barriers. Public and nonprofit venture development organizations (VDOs), such as BioHealth Innovation and St. Louis-based BioSTL, provide services that support the business side of the innovation's development. These services may include space in an incubator, connections to potential customers, funding for IP protections and access to experienced entrepreneurs. NHLBI's EIR arrangement is a positive step toward effective business-side development and could be complemented by arrangements for off-site assistance, with a goal of blending the benefits of expert advice with some serendipitous exposure to other innovative startups and corporations.

Some VDOs and related organizations provide their business services in conjunction with technical development assistance, such as lab space (e.g., BioHealth Innovation's Germantown Innovation Center) and access to university faculty (e.g., University of Missouri-St. Louis's ITE Incubator, supported by BioSTL). Contract or grant arrangements may secure space in these programs for NHLBI investigators to develop their inventions. Many organizations would be willing to work with NHLBI to tailor a program specifically for Institute researchers that addresses particular aspects of federal translation research.

Even well-developed innovations can struggle to scale into a successful product or business if not paired with sufficient executive talent or capital. In addition to providing a range of services to help develop an innovation and business, VDOs are excellent sources of capital access, often through direct seed investments but also by facilitating access to bio-focused investors. From previously noted examples, BioHealth Innovation and BioSTL make direct equity investments, BioAccel in Phoenix hosts an industry-driven challenge, and all have connections to bio-focused investors. For situations where the lead investigator is not transitioning to the startup, VDOs may be best-positioned within the community to connect experienced entrepreneurs to the startup. NHLBI should work with a network of VDO partners as a tool to facilitate the scaling of promising spin-outs.

If the lead investigator is capable and willing to remain with a scaling startup, NHLBI could implement an innovation sabbatical like some Department of Energy and Defense labs are piloting now. These initiatives secure positions for investigators to work with a new company for a set period of time (such as five years). In theory, sabbaticals enable the investigator to take the chance on the innovation without losing the security of a position with the lab. The results for sabbatical programs are not yet clear, as most are relatively new and have received limited use, but based on experiences of some higher education institutions, this approach can have significant results. Even if the programs ultimately do little more than signal the labs' interest in developing innovations, this may help foster a more translation-focused culture.

NHLBI could also achieve improvements in opportunities to scale by collaborating with universities and other nonprofit partners to improve regional entrepreneurial workforces. Partnerships and investments in student entrepreneurship training and curriculum will produce more people with an entrepreneurial mindset in communities — and some of these people may even become NHLBI employees. Examples of

student training include BioAccel in Arizona, which hosts a university workshop series on scaling bioscience startups, and combined living/education experiences like those at the University of Maryland and University of Illinois, which provide multi-faceted approaches to embed students with an entrepreneurial mindset. If NHLBI is able to use grants or other resources to help expand the prevalence of this attitude among students in target regions, it will be able to reap the benefits over the long-term, as some of these students become the entrepreneurs who scale an Institute-generated innovation or perhaps become an investigator or part of the translational research staff at NHLBI.

We are greatly encouraged by NHLBI's interest in pursuing, strengthening or adding initiatives to advance the Institute's early translational research, and we thank you again for your consideration of our response to this request for information. We would be happy to provide additional information on, or connections to, any of the organizations or programs we described. We would also welcome an opportunity to work with NHLBI as it takes steps to implement any of these or other suggestions. These efforts are critical to solving the real health concerns of Americans and continuing the country's lead as a birthplace of innovation.

Sincerely,

A handwritten signature in black ink, reading "Dan Berglund". The signature is fluid and cursive, with the first name "Dan" and last name "Berglund" clearly legible.

Dan Berglund
President and CEO
SSTI