SBIR-IMAT Webinar
April 2014

Christie Canaria: Hello everyone, and thank you for joining us today. My name is Christie Canaria and I'll be moderating today's webinar. I have here with me Amir Rahbar, program director at the NCI SBIR Development Center; and Tony Dickherber, Director of the IMAT program. He'll be speaking about the programs available through the NCI SBIR and jointly with IMAT. We're also joined today by Jennifer Shieh and Brittany Connors from the NCI SBIR Development Center, and together and we are producing today's webinar.

But before we get started, I'd like to point out some housekeeping rules. All of our attendees are on mute, but we still welcome their questions and feedback, so please use the Q & A tool in your WebEx window to send in your questions.

Alternatively, you can send us your questions by email at NCISBIR@mail.nih.gov. Towards the end of the webinar, we will answer your questions, so please send them in throughout the presentation. We will also have a very short poll, which we hope you will fill out as it helps us produce better events, such as this webinar.

And with that, I will turn it over to Amir.

Amir Rahbar: Thank you, Christie. Thank you everybody for attending this webinar about the Innovative Molecular Analysis Technology development for cancer research and clinical care, new PAR. What I'm going to do is go, quickly go over an overview of the NIH SBIR program and the SBIR Development Center and some special initiatives that we have. I'm going to turn it over to Tony, and he's going to talk about the IMAT program. And then we will talk about this collaboration between the two programs and this funding opportunity announcement.

So, SBIRs and STTRs are congressionally mandated programs. They're set-aside programs for small business – SBIRs are set-aside programs for small business concerns to engage in Federal R & D with potential for commercialization. Our budget this year is 2.8% of NCI set-aside, and that will be increasing over the next couple of years. And we also offer small business technology transfer grant, it's also a set-aside program, to facilitate cooperation, cooperative R & D between small business concerns and U.S. research institutions with potential for commercialization.

So we have approximately a $119 million dollar budget annually, here at NCI. The budget will be increasing over the next couple of years, so probably in 2017, we'll be getting 3.2% of the total NCI budget. So it'll be going up over the next few years.

So why seek funding through our center? So this provides safe funding for innovative technology development. It's not a loan, you don't have to pay it back. It doesn't impact, it's not diluted so it doesn't impact shares in any way.

IP rights are retained by the small business. It also goes through a very rigorous review process, so it provides recognition, verification, and visibility that you are able to obtain at an SBIR, so it helps leverage in attracting additional fundings from major capital and strategic partners.

And there are all the bullets. Okay, so the NCI SBIR is a three-phase program. Phase I is feasibility, proof of concept Studies. The guidelines are $150,000 over six months. It could go up to a year, but I'll discuss that later. That's for open SBIR and STTR.

Then we have Phase II, which is the research and development portion of the projects, so commercial basis land is required. How are you going to get this thing out for market, how is it going to change the landscape? The guidelines are a million dollars over two years. And Phase III is a commercial basis stage. We do not fund this. This is used with non-SBIR STTR funds.

Then we also have a couple of other options. We have a fast-track application that combines Phase I and Phase II, application, where you submit both at the same time, and they can get reviewed together. Typically, Phase I, though, they don't require preliminary data. They, it's encouraged, and it's rare that Phase Is are awarded, without some preliminary data.

With fast-track applications, this is especially important. They require much more preliminary data because Phase II is essentially being reviewed by the reviewers, as if Phase I was completed successfully and they don't get a chance to go back and review the progress from Phase I.

We also recently, through the Omnibus solicitation, have a direct to Phase II, so you can skip the Phase I if you already have proof of concept data; basically equivalent to what a completed Phase I would have been. And the hard caps on the award side as mandated by Congress are 50% over the guidelines. So you can go up to $225,000 dollars for Phase I, or $1.5 million dollars for Phase II. Certain awards may see this caps. We have waivers for it, I'll cover that in a little while. And actual funding may vary from topic to topic.

Eligibility requirements are you have to be a solvent concern, organized for-profit U.S. business. That means you have to have 500 or fewer employees, including affiliates. PI Employment Grid of 50% must be with the small business concern at the time of award, and for the duration of the project.

It has to be 50% U.S. owned by individuals or independently operated; or it's greater than 50% owned or controlled by other business concerns that are greater than 50% owned or controlled by one or more individuals; or 50% owned by multiple venture capital operated companies, hedge fund prime equity firms or any combination of these. These are new rules that started as of last year.

SBIR, so provisions for the current Omnibus Grants Solicitation, applicants have to register at SVA, at SBIR.gov. VC-backed companies can now apply, this is for SBIR only, and SBIR only.

And applicants can request $5,000 dollars for technicals that are beyond the award cap. This is money that can be used for things that are generally not used for the projects, like marketing, or preparation of, like an FDA consultant, and so forth.

However, if you request this, you can't participate in the NIH's technical assistance program such as the Niche Assessment Program and Commercialization Assistance Programs, which I'm not going to go into right now, but you are welcome to contact your program directors about these.

The newest provision now implicated—now implemented, as it was said before, there are increased caps for pre-approved waivered topics. At the bottom of the screen, there is a link to the parent solicitation for all SBIR STTR topics at all institutions.

If you look at the, these slides will be made available for you so you won't have to write it down, but if you go to that link, you will see the pre-approved topics that are under this waiver.

So for Phase Is, the caps would be $300,000 dollars in total costs. And for Phase IIs, they would be $2 million dollars total cost. So otherwise, it would be in the normal $225K for Phase I and $1.5 million for Phase II.

And applicants can now switch between SBIR and STTR back and it looks, so you could apply for a Phase II SBIR funding based on a Phase I STTR award and vice versa, and applicants that apply for Phase II B SBIR funding based on Phase II of STTR awards, and vice versa.

And I discussed these recommendations to a pilot program now active for the omnibus solicitation.

So NCIs primary resources for enabling commercial high-impacted knowledge can benefit patients such as all molecule biologics; these are the types of things that we are looking at; major parts of a portfolio. So small molecule, talking biologics, cancer diagnostics, cancer imaging, electronic health and education tools; these are not all-encompassing, however these are our major areas of focus.

Previous to the formation of the SBIR Development Center, the SBIRs were handled by program managers throughout the institute. We put together a new model several years ago and formed the SBIR Development Center.

What we have is a ten-member management team exclusively focused on the administration of NCI, SBIR, STTR portfolio. All we do is deal with the SBIRs and STTRs. The center staff: program director with industry experience and a broad range of scientific experiences. The center co-collaborates with staff across other NCI divisions to integrate small business initiatives with NCI and scientific priorities.

Here's the team. Here are some of us in the room; there I am on the right. There's Christie on the bottom, Jennifer on the bottom. If you'll notice, each of us has a separate for scientific experience and either industry or business experience. So we feel that with these types of skills, we could better facilitate and mentor our grantees.

New activities, the NCI development center, so what we do and what we're responsible for conducting regular outreach events to help recruit more focused commercially-minded SBIR are applicants.

We coach applicants on developing stronger applications. We provide oversight and active management of the projects, and also mentor and guide companies throughout the award period. Beyond that, we facilitate matchmaking with third-party investors and strategic partners so that after the award is over, they can get their, they can get your projects and your products commercialized.

We also have, as I referred to before, our NCI SBIR Phase II Bridge Award. A lot of times after a company has completed Phase II portion of their project, they haven't quite reached a point where they're able to attract third-party funding from investors and venture capitalists. So we have our Bridge awards, sort of crosses what we call the Valley of Death. It provides up to one million dollars per year up to three years, it's open to any NIH fund that's based awardees, and it accelerates commercialization by incentivizing partnerships with third-party investors, and strategic partners earlier in the development process.

And competitive preference and funding priority is given to applicants that can raise substantial third-party funds. So basically matching funds, these matching funds can be anything that just isn't federally, or self-funded. So it could be state funded or venture capital or company or a strategic partner, and so forth.

We also, we try to do it every year or so, put on an NCI SBIR Investor Forum. It's an exclusive opportunity for some of the most promising NCI-funded companies to showcase their technologies. What we do is take our top say twenty companies and put them in a room with around 200 strategic partners and venture capitalists, angel investors, collaborators, and provide one-on-one meetings with them. And our data collected from our 2010, we haven't collected all the data from 2012 yet, but from our 2010 Investor Forum, fourteen companies presented and eight out of fourteen closed deals valued at over $230 million dollars.

So it's a unique opportunity to present your projects to strategic partners, investors, and so forth, and to let them to meet one-on-one with them and focus, get your project commercialized.

We also put on a workshop, we put on workshops, and one of the workshops we do is on federal resources to accelerate commercialization. So basically we bring together NCI, SBIR STTR awardees, and applicants to move technologies from bench to bedside. Our last one was on May seventh, last year. What we do is we bring people in from FDA, CMS, USBTO, OFTP, and let everybody know about resources that are available to them that they might not have previously known about.

So we also have panels on the sources of federal funding, resources and collaboration programs at NIH and unique like science investment organizations. And we provide one-on-one meetings with program directors which is a good chance for them to come and speak directly with program directors who they may have not talked with directly and with the speakers that were

presenting at the conference. At this point, I'd like to turn it over to Dr. Dickherber, who will introduce the IMAT program.

Dr. Dickherber: Thanks, Amir. I appreciate that. Welcome everybody. I'll just give you a quick overview of what the IMAT program is looking to support and then we'll go onto the solicitation itself, as Amir indicated. Next slide please.

So in a nutshell, this is what the IMAT program is looking for. It provides very early stage technology focused development support. For any platform that offers a highly innovative, new way, essentially for measuring and probing molecular and cellular aspects of cancer-relevant biology.

And this has predominantly been done through R21 and R33 award mechanisms, which are shown on the graph, and they're utilized essentially at the Phase I and Phase II level support, much like the R43 and R44 for SBIR award.

And so this new solicitation is the purple one indicated at the bottom of this slide, which is that R43,44, which are independently given or to be given in combined fast-track awarded, as Amir had suggested earlier in the presentation.

So in short, the way that the R21 and the R43 are meant to be considered is as necessarily feasibility study. So they're technology platforms which still require some substantial proof of principal, in order to justify or merit a continued support from the NCI and then going onto advanced development, which can encompass a broad variety of things like scaling the technology, merging it with others, optimizing performance, and so forth. Next slide please.

This gives you a sense for the variety of things that the IMAT program has supported. This is a rather old program for the NCI; it was launched in 1998. And so on either the left column, which represents some of the older technology that came through in the earlier period of the program, many of these have become veritable household names in research laboratories across the country and across the world in many cases.

You may likely recognize a number of them. Probably words that I'm pointing specifically are ones like Illumina B technology, which formed the basis for Illumina's current array of next-gen sequencing platforms was an early stage awarded from the IMAT program. And by the way, the dates indicated in the square brackets are when major commercial milestones or major dissemination milestones were met. Their awards were actually given back in 1998, 1999.

Quantum Dots, the Functionalization of Quantum Dots by the Quantum Dot Corporation, which is now owned by Invitrogen, is another SBIR-related award program. The ones listed on the right side are newer technologies, and some of which have seen a lot of activity of late, certainly RainDance Technologies and Cole TCR, for example, are better known in the community.

And more recently, CellASIC, Onyx, Micro platform, which was purchased a couple of years ago by EMD Millipore, is another SBIR grantee. Next slide please.

So the unique attributes of why the IMAT program solicitations are unique from the broader parent solicitations that are issued by NIH and NCI are that, the difference is that it's focused very much on the earliest stages of technology development. And again, technologies that serve capabilities for molecular and cellular analysis of cancer-relevant biology.

And these are meant to hold a potential impact for anywhere across the entire spectrum of cancer-relevant research. So these are tools and in some cases, methodologies that inherently serve everywhere from basic cancer biology studies and understanding the etiology and mechanisms of metastasis, all the way through to better drug delivery vehicles and treatment protocol and treatment mechanisms.

And also, beyond that, for monitoring post-therapeutic and also even in engaging population-scale epidemiology studies.

This is done, not at the expense of biological hypotheses or hypothesis-driven research, but the focus is very much on the novel technology capabilities with an appreciation for the biology, but not necessarily requiring any significant biological hypotheses to be investigated. In fact, any specific biological hypotheses cannot be supported. The research of those hypotheses cannot be supported through these awards; it must specifically be on developing the capabilities of the tools being proposed.

The other unique aspect is it's very heavily, the review and management of these awards is very heavily weighted, especially at the earlier stages. On milestones that are proposed by the applicant and reviewed by our reviewers are the principal benchmarks for assessing progress on any individual project.

So those are something that I would definitely draw your attention to thinking about and looking at any guidance we have on our website and then within the RFA or I'm sorry within the funding opportunity announcement to consider very significantly in putting together your application. Next slide please.

And just to give you a sense, I mentioned this earlier, some of the early stage success stories from the IMAT program that came through the SBIR mechanism. It is, you know, Mark Chee with the Chief Scientific Officer for Illumina Technologies in the earlier days, and won two different IMAT awards; both progressing through R43 and R44 to develop aspects of their current family of next-gen sequencing platforms. Next slide please.

And Robert Daniel's with Marcel Bruchez; one of the very first SBIR awards to Quantum Dots with Progression Dot was actually from the IMAT program. And that was on the functionalization of Paolo [inaudible's] Quantum Dots.

And obviously the commensurate commercial success was seen to merit the investment [inaudible] corporation. Next slide please.

And more recently, Philip Lee coming out of an academic laboratory with Luke Lee at the University of California to explore this Microfluidic platform they had developed and turned it

into a commercialized cell [inaudible] culturing platform that has a couple of years ago, was purchased at and exclusively licensed I think by EMD Millipore, and has won a number of awards for innovation, including the R & D 100 and the SLAS Innovation of the Year award, for example. Next slide please.

Tried this one, I'll hand this one back to Amir and I'm available for questions throughout.

Amir Rahbar: Thank you, Tony. And Tony, feel free to interject at any point during the presentation if you feel like there's something relevant that you need to say.

Dr. Dickherber: Sure.

Amir Rahbar: Okay. So at this point, we're going to start talking about the PAR. Districts PAR-13327, the Innovative Molecular Analysis Technology Development for Cancer Research and Clinical Care. We call the SBIR IMAT PAR for short. So the background. SBIR Development Center and IMAT programs share the goals of stimulating the developing of innovative molecular analysis technologies.

The scope of the R21, R33 IMAT solicitations are limited to early-stage development; they don't support commercial validation activities. They're primarily academic in focus. The SBIR IMAT PAR seeks to catalize technology, to get technology development and commercial validation of these technologies. So we want to provide a cohesive program that's aligned with the goals of IMAT R21, R33 program, with an emphasis on commercialization; a focus on high-risk cover work projects.

So what we want are IMAT-like projects that, but we don't focus on commercialization. So technology development projects, you sometimes don't fare well when you only use standard SBIR review process. So we put this thing, this application together specifically for technology development.

While IMAT is unique and is structured with our high-risk, high-reward initiative that specifically seeks the development of technology with potential to rebuild the cancer research as it might imply.

Therefore, I got that academically funded projects. So what we want is companies to apply with IMAT-like projects to the solicitation.

So the purpose of the program announcements is to provide a mechanism for small business to obtain funding from for the development of IMAT-like projects with a focus on commercialization.

The announcement is that if that's already been initialed, FOAs, solicitation, soliciting innovative transformative technology development products in the area of molecular and cellular analysis technologies that can advance cancer research with a focus on high-risk, high- reward projects.

It is also potential pipeline opportunity in between its transfer of technology development through the IMAT, R21, R33 mechanisms and on to the SBIR R43 and R44 mechanisms, and on to ultimate commercialization and utilization by a medical community. And I'd like to say that prior participation in the IMAT program is not required for eligibility as FOA.

Applications are expected to indicate the significant attributes and advantages of proposed analogies over currently available technologies, and eventual approaches. So, again, we would expect, while the academic community applies for the IMAT R21s and R33s, we want small businesses to apply for the R43s and R44s through this mechanism. So we've got to think of this as a side-by-side companion to the IMAT program.

So this is the standard pipeline; it's similar to the slide from before. So the R43 Phase I application, they're exploratory, they basically they're proof of concept, requirements is relevant to cancer, quantitative milestones which I'll go over later, truly novel or capability, improvement over the state-of-the-art, commercial feasibility.

For Phase IIs, of R44s, it's the mechanism that developmental validation phase, plus initial commercialization efforts. Requirements are advanced development, and scaling the technology appropriate for cancer researchers and clinicians. Validation for clinical research, with significant impact in the field, and evidence of technical feasibility completed by the end of Phase II. The technology is disseminated by publication, licensing or commercialization. Technology tools for researchers; they can be new, molecular and cellular analysis capabilities, unavailable through other approaches in technology; that are high resolution, more detailed analysis, improved specificity, selectivity, sensitivity, faster processing, better multiplexing, cheaper, faster, better, things like that.

We're looking for tools that can be used for, like Tony said, as with the IMAT it's not hypothesis driven . We're not looking to detect a panel of biomarkers; we're looking for potentially a tool for detecting a panel of biomarkers, and such like that. So this is focused on technology development.

So the scientific scope. The FOA will support researchers at small business concerns, who wish to develop and validate their innovative technologies in the context of commercial use, these technologies could have been invented, discovered, and initially developed with support from any funding source, including, but not limited, to the NCI IMAT program, or maybe an entirely new invention applications.

The technologies are expected to exhibit a high degree of innovations with transformative potential, or otherwise demonstrate clear advantages over currently available technologies, as is required for the application to the IMAT program as I stated on a previous slide.

So I also tell people to visit the IMAT website for more information about these types of programs, because it'll give you an idea of the types of projects that they fund.

Dr. Dickherber: It's worth interjecting is we also keep a comprehensive of all awards ever given by the IMAT program on that website, so you can also look through that.

Amir Rahbar: That's good. So you can get an idea if your project fits within the scope of this FOA. So definition of technologies. Okay, this could be novel techniques, materials, instrumentation, and devices that offer significant improvements in terms of novel cancer-relevant analyses, and/or rate of resolutions, specificity, and/or throughput relative to the career available measures or tools. Highly innovative platforms for sample preparation and/or processing, and for improving the on-stream analysis, down-stream analysis are also in the scope of this FOA.

The proposed technology and application must correspond to an important, unmet need relevant to cancer research and/or clinical aspects. And these technologies, both Phase I and Phase II, must have strong potential for commercial success.

So technology areas that are included, but not limited to, these areas of interest. These are not all-encompassing, but generally when deciding if your potential project is suitable for this FOA, think of these parameters. A technology that's capable of deciphering basic mesh mechanism underlying cancer initiation and progression.

Technologies that enable substantially improved cancer detection and/or cancer risk assessment. Technology is capable of distinguishing assessing, and/or monitoring cancer stage and progression. Tech to facilitate or accelerate the process of drug discovery, or development of generic approaches to improve drug delivery.

Technologies that can facilitate and/or enhance molecular analysis in cancer epidemiology, technologies for sample prep, and/or processing for improved downstream analysis. Tech that can offer a novel means for assessing general analyte quality to determine sample fitness for purpose for a known analytical platform, and technologies or tools that may help overcome various barriers of research; the incidence, prevalence, mortality, and burden of cancer among members of under-served populations. Technologies that are generally not approved for this FOA would be projects describing milestones that do not indicate advanced capabilities or offer progress for commercialization. Projects proposing software informatics solutions, database elements, data mining, the physical tools, and computational mathematical modeling. Projects in which the main thrust of effort is on exploring biological or clinical hypotheses, as Tony mentioned before, traditional hypothesis driven projects rather than on technology development itself.

Projects proposing whole body or in-vivo imaging methods or specific contrast agents, and projects centered on development of specific drugs, and therapies, any kind of drug development projects.

So for Phase I projects, preliminary data is not required, as I said before, but it's strongly encouraged. If preliminary data is not available, the Phase I projects have to based on rigorous scientific rationale. But if you have preliminary data , I highly recommend that you put it in there.

Phase I projects are expected to prove the technical feasibility and possibly generate a prototype if appropriate. And a degree that it's sufficient to support the use of the proposed technology in a cancer-relevant application.

Project goals must be supplemented with specific key technical, commercially-relevant milestones, and quantitative milestones are required; and I will go over that shortly.

Okay, so again, Phase I projects. They need to be innovative, cancer-relevant metrics of success that determine or optimize technical capabilities and anticipate their long-term use to advance cancer research and/or clinical practice. The proposed technology may be targeted technology; the proposed technology must see focus on the initial developments and application of an innovative molecular analysis technology in a biologically relevant system.

Applications must describe the needs of basic preventative diagnostic translational epidemiological health disparity in clinical cancer research or may have the potential for broad use of various skills of research. They need to be substantial improvements and/or new capabilities, so all proposed technologies must offer the potential for substantial improvements over conventional approaches and/or add quantitatively new research capabilities not provided by current technologies. There should be transformative potential. So, defined clearly the novelty of the proposed technology and describe its anticipated use in the laboratory, research, or clinical setting.

Twenty potential impacts are expected to be in line with specific quantitative milestones. It's got to have commercial potential. So clearly indicate the unmet need for the proposed technology describing the marketable product, process, or servers along with information regarding market size and growth projections; and again, quantitative milestones. Quantitative milestones should be carefully selected and precisely defined, and should clearly detail the expected advantages of the proposed approach, relative to the existing technologies.

For Phase II projects, the Phase I results should have already been demonstrated, have already demonstrated technical feasibility of the invention, Phase II projects are expected to concentrate on further technology development and improvements to address intellectual property protection including if you file under patent, put that information in there, even if it hadn't been approved. Preparation of regulatory steps, as applicable, that might be needed for commercial application of the technology, project goals must be supplemented with specific key technical and commercial-relevant milestones, and again, quantitative milestones are required and very important.

So for Phase II projects, what you're going to be doing is validation of the cancer-relevant technology. So applications must focus on the validation and advanced development of an innovative molecular analysis technology that targets basics, that targets the need of basic, preventative, diagnostic, translational, epidemiological, and/or cancer research for the broad potential use in cancer research and clinical use. Provide appropriate background preliminary data to justify the proposed technology and has passed through the pilot developmental stage, and shown promise. Describe strategy and specific research steps to evaluate and rigorously validate the proposed technology within the context of the intended use.

Again, should have substantial improvements, and new capabilities, like before, it should have transformer potential, as described before. Quantitative milestones are expected, just like before, with the Phase Is; there's not any difference. What's important in Phase II is the commercialization plan. All applications must also describe the commercialization strategy for marketing proposed technology as products, service for accommodation or process, or combination thereof.

So commercialization plans should discuss the clear need and window of opportunity within the best specific market. Outline the competitive edge over existing products and services, and outline the key steps that would be taken in a period of support for achieving commercial success. Now I'd like to — reviewers review their scored review criteria on their significance and investigators, innovation, approach, and environment. So we're here to compare and consider each of these review criteria to determine its scientific merit, and give a separate score for each, with their preliminary scores.

An application doesn't need to be strong in all categories to be judged likely to have a major scientific impact; for example, a project that by its nature is not innovative may be essential to advance a field.

With significance, does the project address an important problem or a clinical barrier to progress and, towards progress in the field? If the aim of the projects are achieved, how will scientific knowledge, technical capability and our clinical practice be improved. How will successful completion of the aims change the context, methods, technologies, treatments, services, or preventative interventions that drive this field; does the proposed project have commercial potential to lead to a marketable product, process, or service?

In the case of Phase II, fast-track, to Phase II competing renewal, does this, does the commercialization plan demonstrate a high probability of commercialization? Specific, in addition to this, specific to this FOA as opposed to the Omnibus, what is the potential for the proposed technology to transform cancer research or clinical practice if the project is successfully completed? Are the applications in that area realistic, realistic and in-line with the planned developmental efforts? Do the proposed milestones support a transformative capacity for cancer relevant field research or clinical care?

All right, with regards to investigators. Are there PEs, or PIs, collaborators, and other researchers well-suited for the project? If early-stage investigators or new investigators or in the early stage of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishment that have advanced their fields?

If the project is collaborative or had a multi-P.I. project do the investigators have complimentary and integrated expertise? What's their leadership approach, government-supported and agent structure? Is it appropriate for the project? And next, I'll go into innovation, which is general, but the application challenge had seemed to shift current research and billable practice paradigms by utilizing novel therapeutical contents, approaches, or methodologies, instrumentation, or intervention.

Are the concepts, approaches, or methodologies, instrumentation or intervention novel to one field of research or novel in a broad sense? Is it a refinement, improvement or new application; is there a theoretical contents, approaches, or methodology, instrumentation, or interventions proposed?

I have a little asterisk next to this because there are also specific FOA additional review criteria. Does the proposed technology offer clear and significant improvement over currently available methods and platforms? Will the proposed technology offer new possibilities for cancer research or oncological practice relevant to current methods?

If the project focuses on a new cancer relevant application of an existing technology, how innovative is the new proposed type of technology usage? With regards to approach, are the overall strategies, methodologies, analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? This is very important.

If the project is in the early stages of development, will the strategy established feasibility and will particularly risky aspects be managed? These could be addressed in the Pitfalls and Barriers section of the research plan. If the project involves clinical research, are there plans for number one, a protection of human subjects for research risks, and number two, inclusion of minorities and members of both sexes, genders, as well as inclusion of children justified in terms of scientific goals, research, study, or books.

And finally, they're judged on the scientific environments of the work, in which the work will be done; contribute to the probability of success. Are the institutional support equipment and other types of physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, and scientific subjects, population, or collaborative arrangement?

Okay, and just a word on commercialization plans, these are required for Phase IIs. All applications, also describe the commercialization strategy for the marketing of the proposed technology, of the product, process, service, or accommodation thereof, they should discuss the clear need and window of opportunity within this specific market, highlight a competitive edge over existing products and services, and outline the key steps that will be taken over the period of support towards achieving commercial success.

Okay, now a word about quantitative milestones. Milestones should be well-described, quantitative, and scientifically justified. Discuss the milestones as a means of judging the success of the Phase I project, as well as provide proof of principle for justifying further development efforts under a Phased project.

For example, these milestones at CSU were successful in your Phase I aims. So where appropriate, milestones should include relevant statistical context for the targeted parameter. Like if you say you're going to use fifty blood samples for your technology, where'd you come up with that number? Did you get a bio-statistician to do a power calculation for you?

Listing all the milestones in a single locations is helpful for the review of the application; I suggest listing each milestone after each specific aim; a brief description of it, one or two sentences, and then your quantitative milestones right after it. And then the next thing and then so forth.

So while examples of quantitative milestone; so think of specific aims as how you would define the path you intend to follow to your destination. Milestones provide a way of determining whether you got there. So they're useful in determining the merits of whether or not to award a Phase II R44 application. And so acceptable milestones give a quantitative measure of what a successful outcomes will be. So an inappropriate milestone would be I will characterize, compare, or analyze substance X. There's no way to quantitatively measure whether you were successful in doing that.

So the example of a quantitative milestone will be to have I am going to detect one cancer cell in 10^8 normal blood cells. Or I'm going to detect target analyte at a concentration of one femtamole per mil in [inaudible]. Or detect one mutated gene in the presence of a million wild-type copies. Demonstrate that that technology gives the same result in ninety-five out of a hundred assays, so on and so forth. So you get the picture here. What we need here is a quantitative number that you can tether to your specific aim.

Other opportunities; we are offering for our, obviously our IMAT grantees that are, we're going to go through, it's going to go through a CSR review with [inaudible] panel, so it's not going through a standard study section.

We are going to provide access about information to NIH and NCI resources typically needed for this type of continual development and things such as where are to get biospecimens, standard materials, molecular chemical library, and other tech validation resources. We are working with the FDA to assemble an inter-agency team capable of providing specific guidance and feedback to applicants. And we're also going to provide a quarterly webinar informational sessions for the topics; a topic area could potentially include regulatory activities, tech transfer issues, business development, how to license your projects, commercialization strategies, how to get a strategic partner and fundraising once your topic is done. These are typically things that might not be intuitive to people starting a new company.

Requirements, just go by the standard, SF424. We do not have a direct to Phase II or a direct to R44 allowance for the IMAT solicitation. We do for the Omnibus. We are working on getting one. This will help transition a lot of the IMAT, the current IMAT R21, R33s into the SBIR program. So for again, just as a background, excluding the waiver that I mentioned earlier, for Phase Is, total cost up to $225,000 for two years, 225K for up to two years, if it's a feasibility study, you have to show commercial feasibility at quantitative milestones.

For Phase II, total cost up to $1.5 million dollars for up to three years. At this point, you're doing development and regulatory, and/or regulatory validation studies, if you're at the point where you're doing actual manufacturing and marketing plans, requires proof of feasibility and a good commercialization plan is very important; and the demonstration of transformative utility.

Again, I encourage you to see from the earlier slide, the link, to see if you are eligible for, if your technology's eligible for the waiver. It's listed on, if you go to PDF and just search for waiver, it'll come right up; all the areas of interest that this guide considers eligible for the waiver. If your technology's eligible for the waiver, the total cost can be up to $300,000 dollars for Phase I and $2 million dollars for a Phase II. Otherwise, stick to the caps of $225K for Phase I and $1.5 million for Phase II. I've gone over a lot of this already, so we are accepting Phase I, Phase II, and fast-track purpose grants. They can be new or resubmissions. I've discussed the awards; I don't think I need to go over that again.

The next application due date is May 28, and next slide. You can find more information about this at our website at SBIR.cancer.gov/funding/technology, and again, I'm making these slides available for, besides who was available, for everybody who attended the webinar, and they'll also be available on our website later on for those that didn't. So you don't have to frantically write down the, all these links.

So anyway, more information of the SBIR IMAT solicitation can be found in the first link. The second link is the full funding announcement. I encourage you to take a, to really look at that. That has much more information about the specifics of it. The link to our NCI SBIR Development Center is there, and also, I put the link in for IMAT. As Tony suggested, it may be a good idea to take a look at some of the projects that they are currently funded and have funded in the past, to see if your project fits within the scope of this FOA.

Again, we're not doing hypothesis driven research. I've had people come to me and say I have, I'm developing an instrument that is developing a biomarker panel for the detection of this type of cancer. That's too targeted. We're interested more in technology development; so, developing a technology that would be used for identification of a biomarker panel for a type of cancer, things like that. So, Tony, do you have anything to add?

Dr. Dickherber: No I don't. But certainly happy to answer any questions.

Christie Canaria: All right. So thank you, Amir, and Tony, for today's presentation. I also want to thank our guests who are joining us today online, thank you for staying with us. I also just want to chime in and add that if you want to contact our office regarding your application for this program, please do so at least a month in anticipation of the deadline. So we are here to help you, so feel free to reach out to us. Next, we are going to open up the panel for questions, but please use the Q&A tool in WebEx, and we are also going to open up our poll. So if you can please take the time to fill out to fill out our very short questionnaire. This helps us justify programs like these webinars, and to help improve them in the future. So with that, we will open up for Q&A.

Brittany Connors: Hi everyone, my name is Brittany, and I will be asking the questions that I've received in the Q&A box. The first one that I have is do matching funds from a research foundation not government count as matching funds?

Jennifer Shieh: The Phase IIB Bridge Award. And my answer to that is yes. This is Jennifer Shieh by the way.

Brittany Connors: Okay, so the next one is can we apply to IMAT using direct to Phase II?

Amir Rahbar: Yeah, we are working on that. We just got it out the direct to Phase II out for the Omnibus. We can't just make it an addendum to the IMAT-SBIR solicitation. We have to actually put out a specific direct to Phase II FOA. We are working on that, and that is in progress. I recommend everybody sign up for updates on our website so that when that does come out, you will know as soon as we do.

Brittany Connors: Okay, so the next one. Is there a Direct to Phase II pilot program in place for SBIR R44?

Amir Rahbar: For the IMAT SBIR or for the Omnibus announcement?

Jennifer Shieh: I would interpret the question to be just in general, so there's a specific direct to Phase II broad Omnibus pilot FOA, so it's not through the Omnibus itself. But there is a separate funding opportunity announcement. And if you go to SBIR.cancer.gov, you can find information and links.

Amir Rahbar: Yeah, the top on the right side, there'll be latest announcements, and there's the link to the Direct to Phase II announcement. And it has the requirements of what you would need to be eligible. You know, at what stage your project would need to be to be eligible for the direct to Phase II, so a lot more information there.

Christie Canaria: And this is Christie. I want to just chime in again and remind you that their next due date for the Omnibus is actually April 7, which is next week. If you'd like to apply for the Direct to Phase II at the next cycle, although that will be due on August at 2014. But again contact us at least a month in advance, with your questions about your application.

Brittany Connors: Okay, so next we have is assay development considered part of the technology development, too, or does IMAT fund only hardware and software development?

Amir Rahbar: Assay development. Tony, are you still there?

Dr. Dickherber: Yeah, yeah. So I think the question to ask yourself then is what is the new piece that you're proposing to build? Because if the new piece you're proposing to build is a specific assay where you've identified some sort of a signature that you want to be able to detect, and you have a technology that's capable of detecting that signature as long as you guessed the signature right, then inherently, you have a biological hypothesis you're pushing.

And for us, the way we think about it is, would be measurement capabilities. Are these the things that are new or is the question whether or not the biology is there to measure. If the question, the answer to that question if there's a new technology deepened, then that's within IMAT's scope. And it could be that just the nature of what you want to measure is such a very specific thing that would be left up to the review to decide essentially whether or not what you proposed has a broad transformative impact for cancer-relevant research. Or if it is a one-off specific thing that

really wouldn't have perhaps as broad a potential as many of the other applications being considered. And so you're inherently disadvantaged in that way.

Amir Rahbar: Yeah, that goes back to what I said before. If you assay a specific for like a disease condition or specifically to detect a certain type of cancer, then the solicitation probably would be considered non-responsive, the solicitation. But if you're developing an assay that can be generally used to detect protein and that can be used for biomarker development or whatever, molecular analysis or cellular analysis, that's fine. It just needs to be more general. We're looking for new tools in a tool kit that scientists can use to advance cancer research and clinical care. So the specific sort of biomarker assay, you know, and so forth, would be non-responsive to this FOA.

Brittany Connors: Could you please talk about how to collaborate with NIH intermural program?

Christie Canaria: Oh, sorry. Tony, go ahead.

Dr. Dickherber: Well, so, there's a fairly strict line between what we consider extramural versus intramural funding, so awards are given to support research among laboratories and investigators outside of the NIH, and that's the pocket we consider extramural. And internally, there are a number of laboratories doing work that are within federal labs done by federally-employed scientists and engineers. And those two groups can collaborate, but money, with very rare exceptions, can never change hands from funding that went to support extramural research and funding which has supported intramural research.

Jennifer Shieh: If you are interested in collaborating with an intramural lab, I would suggest that you contact the lab directly, or talk to the NIH office of technology transfer, or if it's an NCI intramural lab, the NCI technology transfer center, which assist at putting together their formal agreements for research collaboration. And it is true, SBIR funding and extramural funding cannot go to intramural labs. But you can use other funds to pay those labs that might be freed up by having the SBIR or STTR award. And there are also, if you go to the SBIR.cancer.gov website, and look at the, there are also resource, contract resources that are not intramural labs per se, but resources that NIH provides that can assist in some of the clinic lab validation or other kinds of work. And you can find those on our resources, in the resources section of our website.

Christie Canaria: So those may include programs to do in-house [inaudible] bridging development gap, we do programs like that. And those are outlined on our website as Jennifer said.

Dr. Dickherber: I should also, and just make sure it was clear, that those collaborations are possible, intramural and extramural, and an award can be given to an outside group which necessarily involves in a quite significant way, collaborates with an intramural investigator and an intramural lab. But it is a unique thing and does require significant additional paperwork to manage.

Brittany Connors: Okay, so the next question is it possible to apply simultaneously to R21, R33 and SBIR?

Dr. Dickherber: Yes.

Brittany Connors: Great. Can professional services expenditures be included in the budget?

Amir Rahbar: Wait a minute, I'd like to address that last question.

Brittany Connors: Okay.

Amir Rahbar: It can't be the same application.

Dr. Dickherber: Yeah, as standard NIH rules for non-duplicate applications in the same cycle apply, but if they're different ideas, then, substantially different anyway, then there's nothing preventing you from having actually several applications in all three rounds, in all three areas.

Jennifer Shieh: As a follow-up to that, proof and assay the question wanted to know about whether the academic partner applied for the R21, 43, and the small business applies for the R43, for the SBIR STTR mechanisms?

Dr. Dickherber: Go ahead, Amir.

Amir Rahbar: I was going to say a company is going to apply for IMAT grants, correct Tony?

Dr. Dickherber: Yes, yes, absolutely.

Amir Rahbar: So the academic institution and/or a company can apply for R21, R33. But for this FOA, the small business has to be the applicant for this kind of SBIR collaboration FOA that we're talking about.

Dr. Dickherber: Right. So depending on what was being asked of that question, as Amir was saying, what's unique and interesting to this community about this FPAR that we've been talking about, is that it is uniquely only open to small business entities, whereas the IMAT R21 and R33 solicitations are open to any entity. In fact, it's an internationally open competition. If what was being asked was could you somehow leverage awards through R21 and R43, 44 to be complimentary in some ways such that they're additive and perhaps somewhat codependent, that would present a very interesting review challenge, because I'm not really sure how you would let one review group know about the other application or if that was important or not. So I, if you have more questions more about this, I would encourage you to contact me or Amir directly and we can try to sort out exactly which what you had in mind.

Jennifer Shieh: And I have just one more thing to clarify, if the question was if you have an academic partner or one in particular project that you would like to apply that has an IMAT technology, then, and you are the small business. You apply for the SBIR IMAT if it's appropriate. Your academic partner can be your partner on that SBIR grant, or STTR, especially

if it's a, this is SBIR linked. So if your academic partner can be still a partner on that project, if it makes sense for that project, when you apply as the small business to the SBIR funding opportunity.

Amir Rahbar: So you're explaining that this academic partner already has an IMAT grant…

Jennifer Shieh: No, no. If, I was just explaining, if your, I'm not sure if I fully understand those questions that we're trying to explore all of the possibilities. There's a question in, you have an academic partner. There's one project, but you're partnered with an academic institution. If there's one project, you apply only together with that partner to the one funding opportunity. You don't split them.

Amir Rahbar: No, no. I mean, it's not uncommon for SBIRs to have academic partners. Academics have accesses to resources and animal facilities and samples all the time, you know, that small businesses commonly use in their applications. So the small business would be the applicant and the academic partner could be a collaborator, co-investigator, or so forth. You just have to follow along with the rules.

Brittany Connors: Okay. Can professional services expenditures be included in the budget?

Jennifer Shieh: So this is, and it depends about what professional service is, Amir was just talking about.

Amir Rahbar: It would have to be research related. You can't hire an FDA consultant. You cannot hire, you can't use it to put together your patent application. Professional services such as CROs or like animal facilities or manufacturing. Or like you design the kit, so then you get some other company to manufacture the kit for you in Phase II or something like that. That's fine. But there are a bunch of limitations to how much has to be kept, to be spent, for each of the phases.

Dr. Dickherber: I was just going to say at the bottom of the solicitation, you'll find the context information for the grant specialist for any given solicitation and they can help you sort through some of those questions.

Jennifer Shieh: And then if there is a professional service that, you know, Amir mentioned, for example, FDA regulatory consultant; if that's the type of professional service you're talking about, you can request an additional $5,000 dollars for technical assistance, that does not count towards your regular research budget. And that type of professional service, so assistance for FDA regulatory consultant or marketing assistant or things like that kind of professional service; you can request to that, and it is a separate part of the budget. And it's a separate up to $5,000 dollars.

Amir Rahbar: That's what I had talked about on one of my earlier slides.

Christie Canaria: And there's also a space in your budget for a 7% fee that you can include. This would be the part within your total budget though, so there'd be total, direct, indirect plus this 7% fee helping. And that money can be used for those similar types of activity.

Amir Rahbar: Right. The fee is just, you know, you're a company, you need to stay in business, and so you can apply up to 7% and that fee can be used for whatever.

Christie Canaria: And it's important to note that when you submit your application, you need to include the fee and/or the technical assistance request in your application. Because once you've been awarded, you won't be able to go back retroactively and request it.

Amir Rahbar: Yeah, and so a lot of people are not aware of this fee. But the fee counts in the total costs, whereas the fee for technical assistance does not.

Brittany Connors: And that's just sort of follow-up someone asked do you have a limit for a number of consultants?

Amir Rahbar: I don't know if there's a limit for a number of consultants, but there's a limit to how much can go to them for…

Christie Canaria: For Phase I, at least two-thirds of the work of the effort needs to be accomplished by the small business, and for Phase II, that's 50%, and so when you build your application and your proposal, you should reflect that you fall within those guidelines.

Amir Rahbar: So, we basically don't want a virtual company, where you're outsourcing 95% of the work and just managing it from a small office. So two-thirds of the work has to be done, two-thirds of the money, has to be done; the work has to be done at the small business. The other third can be towards contracting or if you need an animal facility, or for an academic partner, or whatever, a CRO or manufacturing, you know, whatever, for Phase I. For Phase II, it's 50%.

Jennifer Shieh: And just the, so this will probably be very private dependent how your consultant is viewed; whether that consultant is part of, considered to be part of your small business versus a contractor or a sub-contract that would not count towards the work that's going in from your small business. With the specifics of your project, you may want to contact the grants management specialist that's listed on the FOA.

Amir Rahbar: Right, and then that consultant, they also may just be somebody providing blood samples. They also may be somebody just providing an expert in the field. Let's say you had a project that involved a certain type of indication and you were typically an engineering company, developing an instrument, the consultant could be the consultant in that area of expertise, such as immunology or cancer or a certain type of cancer or so forth. So the consultant isn't always a CRO or manufacturing institution, it could be a person, literally just consulting on the project, an expert in the field of engineering, of this, of that. So you know, you want to make sure, one of the things you're judged on is are the investigators. So you want to make sure you have every area of expertise that you're going to need on, covered by either somebody on the grant either by effort or through a contract or through a subsequent consulting or a letter of support. Like what I said about the biostatistician, you know, he could say we're going to look at fifty samples; they're going to say how did you come up with that fifty samples? Fifty may not be enough to prove feasibility for this particular, for whatever, for this particular instrument so that it would

validate a Phase II effort. So in that case, you would get a consultant, hire a, the consultant would be the biostatistician, he would say you would need at least eighty samples, maybe so and so disease and so and so control. So a consultant's going to be, can do different things.

Brittany Connors: Okay. And a follow-up also, can we include chemical synthesis as region cost versus going toward the two-thirds and how does that work?

Amir Rahbar: That goes toward material and supply, so, yes. I think that, because it's not all just effort and salary. If you were purchasing something and it's coming to your company and you're working on it there, the money if you're talking about like ordering reagents for your instruments that you need to, if you're spending it in-house, it's fine. It doesn't count as going out to outside consultants. That's what you're asking.

Brittany Connors: And is this the appropriate funding mechanism for clinical trials?

Amir Rahbar: I would say no, this is technology development, so hopefully they could use your instrument in clinical trials later on, or your assay, but this is not, this would not be appropriate for clinical trials or drug development, and so forth.

Jennifer Shieh: But if you're doing a validation of your technology, and that's what you mean by a clinical trial? Using human specimen for validating the technology, would this be appropriate?

Amir Rahbar: I mean, for a full-scale clinical trial, I mean, Tony, what do you think? I mean, this is not. What we're looking for is technology development, and with technology development, you're going to need to run fifty or a hundred samples on your technology to show that it's working. You know, ninety-five out of a hundred samples came within CVs of 5%; that was your milestone. So that's not a clinical trial, per se, but you're running it on clinical samples.

Dr. Dickherber: One thing I've certainly heard is that certain kinds of assay validations which would be part of validating the strength of the new device is part of what people consider pre-clinical trial. If you think about the nature of where technology has to be to be within the scope of what would get supported and what would be competitive in the review, it's unlikely that the award is sufficient to get you through all of that development and pay into a significant clinical trial. That said, I don't think there's anything that specifically bars clinical trial roll out of anything that is developed and use the money to support some of that. But I would consider it unlikely that it's ready for that.

Christie Canaria: All right. Thank you everyone for joining us today. We've run out of time, so this is the end of our webinar session. Again, please feel free to contact the NCI SBIR Development Center via email, or by phone, you can also visit our website for more information. In addition, feel free to follow us on Twitter at @NCISBIR or on LinkedIn. So thank you again and just to note, we will be able to post these materials on the website and mail them out to you in about a weeks' time. So thank you again for joining us.

[End of Recording]