

THE CONAFAY GROUP

GOVERNMENT RELATIONS ● SCIENTIFIC PERSPECTIVE

TO: Participants April 30, 2020

FROM: Jessica Kenyon, Senior Vice President

RE: Frequently Asked Questions (FAQ) from webinar entitled "Understanding COVID-19 Medical Research & Development Opportunities"

This document addresses the questions we received from participants in the webinar noted above. Questions we received that were specific to individual research efforts are not addressed here. If you have further questions, we suggest private discussion and that you reach out to us at events@conafaygroup.com or your existing Conafay Group point of contact.

What are the current funding levels across the agencies for COVID R&D?

As of today, new funds appropriated for R&D related to COVID-19 total more than \$16 billion.

What funding opportunities have been released related to COVID-19?

Medical R&D funding opportunities in COVID-19 have been released by multiple federal agencies. For more information with hyperlinks to open announcements, please refer to our presentations slides, which are available [here](#) for download. Please be aware that new funding opportunities are being released frequently and more have already posted since our webinar. For more information, please reach out to us directly. Also, we recommend you continue to monitor agency websites as well as [grants.gov](https://www.grants.gov) and beta.sam.gov for the latest information.

For each of the specific agencies, what are the characteristics of the products or R&D they would like to support?

The Biomedical Advanced Research and Development Authority (BARDA) is most interested in near-term solutions that can be used now or within the next 6-8 months when the next wave of novel coronavirus infection is expected to hit. This means preference will be given to products which already have or are very close to regulatory approval or Emergency Use Authorization (EUA). Current DoD opportunities are seeking similarly near-term solutions. The National Institutes of Health (NIH) and the National Science Foundation (NSF) will consider funding longer-term efforts, including basic science.

We urge you to download our slides [here](#) for a high-level listing of the kinds of products and technologies being sought by each funding agency. Please be aware, however, that agency priorities can change rapidly. We urge you to reach out to us with questions and to monitor agency websites, [grants.gov](https://www.grants.gov), and beta.sam.gov regularly.

What are the best mechanisms to engage with the various agencies?

This varies by agency. As a rule, each one is swamped right now, not only by the COVID-19 response effort, but also by the number of communications they are receiving from the research community about potential solutions. It will be harder than usual to reach many in the government during this time.

For specific recommendations, we urge you in all cases simply to contact us as it may be the fastest way not only to understand your best and most likely target but also understand how to approach that communication strategically. Also consider that because of our extensive interaction with the various agencies, we may know the answer to your question outright, saving you valuable time.

Additional thoughts:

If you have a near-term solution, consider applying for a virtual [“CoronaWatch”](#) meeting with BARDA to get feedback before submitting a white paper to their Broad Agency Announcement (BAA). We do not advise submitting a white paper without first requesting one of these meetings. For the BARDA EZ BAA, we urge you simply to submit an abstract as they are reviewing these quickly and providing fairly rapid feedback.

For the DoD, you can reach out to the [Medical Technology Enterprise Consortium \(MTEC\)](#) or the [Medical CBRN Defense Consortium \(MCDC\)](#) for discussion about their posted opportunities.

For NIH opportunities, if you already have an active grant, we urge you to contact your Program Director to discuss the possibility of additional funding for COVID-related work, and sorting out the differences between what would be considered within the scope of work (and suitable for an administrative supplement) versus an expansion of the effort (which would best be covered by a Competitive Revision). Be sure also to check the [NIH Guide](#), or the [NIH's COVID update page](#) for announcements of new opportunities.

The NSF is prioritizing COVID-19-related submissions, so be sure to identify a grant application that may be eligible for this consideration, as well as a more rapid review.

Again, please refer to our slides, downloadable [here](#), for additional information.

Can you offer any tips for best practices on putting together a COVID-related proposal to the U.S. government?

This depends on the agency in question; they all have different expectations and requirements for proposals and grantsmanship, but in this emergency situation, speed - while preserving rigor, reproducibility, and transparency - is a key driver. If you are proposing a near-term solution to an agency like BARDA or the DoD, be very clear about what your solution is, how it could be useful against COVID-19, when it could be used (think now or in the next 6-8 months), and what evidence you have to support those things. Be sure

you are including a clear “ask” that includes research and development because that is what these agencies are authorized to fund.

There is also a real need to better understand the life cycle of the virus and make projections for future outbreaks. So, longer-term research will be of interest, but must have a clear relationship to minimizing the spread and severity of COVID-19 disease. Such opportunities are likely to emerge over the next few months with different mechanisms being favored by different agencies.

For the MTEC call, how detailed the budget should be and is there any idea of roughly how much they're likely to fund per each proposal?

At the enhanced white paper stage, which is equivalent to a pre-proposal, you will not be required to submit a detailed budget, but only a Rough Order of Magnitude (ROM) cost. If they like your enhanced white paper, you will be invited to submit a detailed cost proposal. Please refer to their Request for Project Proposal (RPP) documents for more detailed instructions.

It is not yet clear how much MTEC will spend per proposal, but we expect to know more soon. Please feel free to reach out to us for updates.

UPDATE 4/30: We are anticipating that MTEC will spend \$15-20M on sensor-based diagnostics in their upcoming call.

Have DoD funders (DARPA, Air Force, Defense Threat Reduction Agency (DTRA), etc.) supplemented their application review staffs? For example, have they onboarded contractors to help them separate the wheat from the chaff?

We know that organizations such as DTRA maintain a large stable of contract support staff to help with proposal reviews and anticipate that they will be taking full advantage of these capabilities.

Does the recent MTEC White paper request announcement with the quick 48-hour turnaround time also includes diagnostics, or is it just for therapeutics?

To be clear, the MTEC has only released one Request for Project Proposals (RPP) so far (as of today) and this is only in therapeutics. It has a two-week turnaround. The MCDC, however, released a formal Request for Information (RFI) which suggested submitters supply responses within 48 hours. However, that was not a requirement, and they will continue accepting submissions until the end of May. This MCDC RFI did include diagnostics.

Have MTEC and MCDC become the acquisition arms for the DoD for COVID-19 funding opportunities?

The MTEC and MCDC operate through Other Transactions Agreement (OTA) mechanisms, which offer the fastest review and award process the DoD can use. This is why they are using MTEC and MCDC more and more often, especially now, with all the urgent requirements associated with the COVID-19 response.

We may still see DoD opportunities posted through more traditional mechanisms. Also, note that acquisition implies procurement, which is distinct from R&D in the DoD.

Is predictive analytics of interest to BARDA? What about surveillance?

Not at present. BARDA is focused on present urgent needs such as therapeutics, vaccines, and diagnostics. Thus far, the DoD has specifically called out predictive analytics as an interest area and it is listed as a topic in the “Notice of Special Interest” for supplements/revisions to grants funded by NIGMS, as well as in the “Dear Colleague” letter from NSF. DoD is interested in disease surveillance, as is the Centers for Disease Control (CDC) which recently closed an announcement that sought population health-based surveillance efforts. The appropriate agency really depends on the type of surveillance in question.

What happens to opportunities beyond COVID? Is there still interest in other research areas?

Yes, and most programs do continue to release announcements as they usually do or to follow standard submission deadlines. However, you may find it difficult to get individual attention from some government offices on other topics, just because they are still so focused on COVID. You should still be able to reach your NIH program officers throughout the institutes.

If we want to talk to you about ideas, how do we do it?

If you are already a client, please reach out to your regular point of contact at the Conafay Group. If you are not a client, please reach out to us anytime at events@conafaygroup.com.