

Webinar Transcript

Antimicrobial Resistance: CARB-X Partners Addressing a Global Health Threat

Speaker: Kevin Outterson
Executive Director, CARB-X
Professor of Law, Boston University

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Hello, everybody.

On behalf of all the CARB-X team, we are thrilled and honored to be the recipients of continued support for funding the pre-clinical pipeline here at CARB-X from our founding partners, BARDA, Wellcome, and of course, NIAID.

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I remember maybe six years ago, almost to the day, in which there was a meeting here in Boston, including BARDA and Wellcome Trust, to come together in the partnership that became CARB-X.

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So it's appropriate that here, six years later, we are reconvening to have the happy announcement that funding has been secured for the future.

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Now, to kick off our celebration, we have a five-minute video that will give you some background as to what's going on at CARB-X. When my granddaughter was born, she had difficulty breathing and she had an infection.

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She was transferred quickly to Boston Children's Hospital. And for a couple of days in the NICU, we were preparing ourselves for the worst. But she took a powerful course of antibiotics and her infection cleared and her lungs recovered.

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Now she's just a happy, fully healthy and energetic student in kindergarten. Antibiotics are miracles. They not only treat bacterial infections, but they enable everything in modern medicine. They make surgeries, cancer treatments, organ transplants, and many things safer.

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Every year, 250M antibiotic prescriptions are used by Americans and billions more globally. But we are losing these life-saving drugs. Drug resistance destroys the antibiotics that we relied upon just five or 10 years ago.

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And the death toll keeps rising. Today, drug-resistant infections are estimated to kill over 1.2M people every year around the world.

Webinar Transcript

[Antimicrobial Resistance: CARB-X Partners Addressing a Global Health Threat](#)

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That's more deaths than from HIV/AIDS or malaria. Antimicrobial resistance is a serious top-tier health threat. And the world needs to wake up.

Speaker: woman's voice

While the world needs these life-saving drugs, no new class of antibiotics has been launched in decades.

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Without profit, small companies have been filing for bankruptcy, and large pharmaceutical companies have shut down their antibiotic development. The future of antibiotics looked grim.

Speaker: Gary Disbrow, PhD

Chief of Research and Development, CARB-X

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In 2016, BARDA and our partners at NIAID and the Wellcome Trust catalyzed a public-private collaboration with Boston University called CARB-X. Together, we developed a platform to help spur antibacterial development and revive the then collapsed preclinical research and development space.

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And we are proud to support this program with our partners from the Wellcome Trust, the German and UK governments, the Bill & Melinda Gates Foundation and NIAID.

Speaker: Erin Duffy, PhD

Chief Research and Development, CARB-X

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Together, we support much-needed innovative products for patients. We take a comprehensive approach. The CDC and the WHO developed lists of resistant bacteria that pose the largest health threats.

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At CARB-X, we support new treatments that target these dangerous bacteria. We also support new and rapid diagnostics. Quick test results enable doctors to diagnose and prescribe effective drugs to save lives and slow the spread of resistance.

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We support vaccines and other preventatives because as we've learned with COVID, the best infections are the ones we never have.

Webinar Transcript

Antimicrobial Resistance: CARB-X Partners Addressing a Global Health Threat

Speaker: Cheryl Moore Gary
Director of Research Programmes, Wellcome

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CARB-X is revitalizing the world's AMR product pipeline by assisting product developers around the world, such as Bugworks, a small biotech in Bangalore, which is developing a novel first-in-class antibiotic that can kill multidrug-resistant Gram-negative bacteria.

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Another company in the CARB-X portfolio, Baebies, is working on a rapid test to accelerate the diagnosis and treatment of neonatal sepsis, a leading cause of death in infants, especially in lower- and middle-income countries.

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And we're deeply grateful for the work that the Jenner Institute is doing to produce an affordable vaccine for gonorrhoea.

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These are just a few examples of the many developers that CARB-X has helped.

Speaker: Gary Disbrow, PhD
Director, BARDA

Making a new antibacterial product is no easy task.

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Historically, it takes more than ten years of R&D and over \$1B to translate an idea into a drug that can be used by patients. Our funding will allow companies to access not just non-dilutive funding, but also a full suite of technical and business support, preparing them for advanced development to get them to the patients.

Speaker: Kevin Outterson
Executive Director, CARB-X
Professor of Law, Boston University

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In 2016, Lord Jim O'Neill's review on antimicrobial resistance ignited global efforts to address these threats. O'Neill estimated that the world needed four breakthrough antibiotic therapeutics approved by regulators every decade.

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If we start with more than 1,000 therapeutic projects, only 150 of those are estimated to make it to the hit-to-lead stage.

Webinar Transcript**Antimicrobial Resistance: CARB-X Partners Addressing a Global Health Threat**

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Of those, we estimate about 20 projects would begin first-in-human studies and result in the four breakthrough antibiotic therapeutics that we need. CARB-X is one part of the solution, a key link in the chain of drug development that will eventually deliver life-saving products to every patient in need.

***Speaker: Erin Duffy, PhD
Chief Research and Development, CARB-X***

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It's important to say the CARB-X model is working. Since inception, 11 projects have begun or completed first-in-human studies. Furthermore, two rapid diagnostics have graduated the program, and are now available in Europe.

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Today, we are incredibly excited and grateful to announce new funding from BARDA and the Wellcome Trust. This funding will support the companies currently in our portfolio and hopefully new ones as well.

***Speaker: Kevin Outterson
Executive Director, CARB-X
Professor of Law, Boston University***

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CARB-X intends to do its part, partnering with all stakeholders in the preclinical and Phase 1 space to get closer to a world where no one dies needlessly from a bacterial infection. So we're immensely grateful for the commitment of up to \$300 million from BARDA and \$70 million from the Wellcome Trust, which will help us to continue to fund this amazing program going forward.

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We have a panel now to help us discuss some of these issues and what CARB-X will be doing in the near future. The panel, I'm delighted to say, is led by Ghada Zoubiane, and she's the Head of Partnerships and Stakeholder Engagement at ICARS.

There, she shapes and delivers on their mission, which is to bridge the gap between evidence and practice and works in close partnership with low- and middle-income countries. She's always had a strong appreciation for the science-policy interface.

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And her role includes outreach and advocacy, as well as advising on ICARS strategy. Over two decades of experience in both the public and private sector, leading and executing research strategies at national and international levels.

Webinar Transcript**Antimicrobial Resistance: CARB-X Partners Addressing a Global Health Threat**

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Ghada was previously the Science and Innovation Lead for AMR Wellcome, which is how I came to know her. And she spent over nine years before that with the United Kingdom Medical Research Councils developing their AMR, infectious disease and public health research areas.

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During that time, she also established their AMR Cross Council Initiative, the Funders Forum, and was on the JPIAMR Management Board. It's hard to say what is it exactly that Ghada has not done in the past couple decades. But here she is today to help lead us with this panel. Thank you.

Speaker: Ghada Zoubiane, PhD***Head of Partnerships and Stakeholder Engagement, ICARS*****00:08:07.080**

Thank you very much, Kevin. And I'm really delighted and excited to be moderating this panel of representatives from CARB-X and its founding members. We are joined today by yourself, Kevin, the Executive Director of CARB-X and Professor of Law at Boston University. We're joined as well by Dr. Erin Duffy, Chief of Research and Development at CARB-X.

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Dr. Cameron Bess, Project Officer in the Antibacterials Branch of the Division of CBRN Medical Countermeasures at BARDA. Dr. Tim Jinks, Head of Infectious Disease Intervention at Wellcome. And via our pre-recorded video with Dr. Dennis Dixon, who is the Chief of Bacteriology and Mycology Branch at NIAID.

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And welcome to all those over 300 people who have joined and are listening to this celebration. Kevin, I'm going to have to start with you. Really, we are witnessing and celebrating today the continuous success of CARB-X. But maybe we should start by asking you: Where is CARB-X now? And what are the latest developments beyond what we heard on the video?

Speaker: Kevin Outterson***Executive Director, CARB-X******Professor of Law, Boston University***

The success is really of all the product developers that we're supporting.

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And I'm just grateful to be part of that process of making those projects go forward. But for CARB-X, I mean, mostly there's continuity here. We remain focused. We're not dramatically expanding or changing our focus in any significant way. We are a more mature

Webinar Transcript**Antimicrobial Resistance: CARB-X Partners Addressing a Global Health Threat**

organization now. When we started, first launched our rounds, I think we had four people working for us.

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And now I think we're at 24 or 25 today. And so now we're able to deploy a full portfolio strategy, a strategic plan. We're planning now new rounds that we can launch with this funding. We've updated our governance, because we're a more mature organization. We've expanded some of our footprint in Europe.

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Damiano de Felice is now joining us as a Director of Development and Engagement in Europe. And we are exploring some thoughtful additions to our Global Accelerator Network. And we might be looking for a couple of things there. But the big picture is that we're going to continue to do what we think we do best and what we're doing now.

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And we're going to remain very focused on our current strategy.

Speaker: Ghada Zoubiane, PhD

Head of Partnerships and Stakeholder Engagement, ICARS

Thank you, Kevin. You do have a healthy portfolio of companies currently that CARB-X is supporting. Would you share with us if you're seeing any progress as these companies have started and progressing through the pipeline?

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And is there hope for patients any time soon?

Speaker: Kevin Outtersen

Executive Director, CARB-X

Professor of Law, Boston University

There's certainly hope. There's a lot of amazing science. The great limiting step in this world is the economics, the cash, not the science, in my view. But just this morning, there was a press release about GARDP is supporting some projects at the Phase 1 study that Bugworks is undertaking. And, you know, it was almost exactly five years ago, July 2017, when we first announced our support for Bugworks.

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And that application happened six or nine months before that. You know, these things do take time. We're grateful that we've invested five years and lots of money and lots of other technical

Webinar Transcript**Antimicrobial Resistance: CARB-X Partners Addressing a Global Health Threat**

and business support with Bugworks. And now they're at the moment in which subsequent downstream partners like, GARDP, are also now financially supporting them and helping them, which is a tremendous step forward in my view.

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But Erin, I've talked too long. I'm sure you have other things to say.

Speaker: Erin Duffy, PhD

Chief Research and Development, CARB-X

To build on what Kevin said, we're all about taking programs from the earliest stages, not the basic science. But once they've identified something in treatment that looks like a hit, or in vaccines, they think they know what the antigens are, or in diagnostics where they have an idea that they can really prove out the feasibility of.

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But the idea then is to take those through to a value point that advanced developers can appreciate and want to support. And so, we've done that. Bugworks is an excellent example from when they came in, which as really at the earliest stages of this project to delivering a first-in-class, new antibiotic with a novel mechanism of inhibition.

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And here we are cheering them on in their first-in-human studies. And now seeing as Kevin said, that GARDP is coming in. But as I said in the video, we've had several successes in terms of maturing projects. And so in the first-in-human space, we've had 11, as we've mentioned. Now let me just highlight a few.

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So in the prevention space, actually, this was an earlier investment of ours, we invested in a live biotherapeutic program that was focused on recurrent *C. difficile* infections. I'm proud to say now that our partners BARDA are supporting the advanced development of that program, which is, I believe, ending the Phase 2 period.

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So that's a big success. Also last year we supported a program from GlaxoSmithKline, so it's important to say we'll fund anything from anywhere as long as it's great science and has a great team behind it. In this case, this was a story of an idea that started at Washington University, funded by NIH grants, which was a novel anti-virulence inhibitor of something called FimH, which is meant to stop bacteria from binding to the bladder and therefore prevent recurrent UTIs.

Webinar Transcript**Antimicrobial Resistance: CARB-X Partners Addressing a Global Health Threat**

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And so that program completed its first-in-human successfully with us. And now they are investing in that program in a Phase 1 B study. So lots of activity across the pillars. And also with our diagnostics, as we said, we have two projects that graduated that are for sale in Europe.

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Really neat stuff. One of them gives you automated susceptibility testing in less than 4 hours, which is really great from a positive blood culture. And the other, which has expanded its offerings of a resistance panel. So we all know bacterial ID is one thing, but understanding the resistance genes that are present are really critical.

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And they expanded their menu to 13 direct from whole blood. So again, really exciting stuff. Well, you asked about the challenges. You know, our teams, GlaxoSmithKline is on the far end. But a lot of our teams are these micro companies, 3 to 5 people, sometimes setting up shop in a storage bin. I'm kidding you not. I actually visited a place like this. But they have passion for what they do. They often don't have all of the disciplines or the expertise to translate those ideas into drugs or other products.

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And so we build support teams around them of subject matter experts, both from our internal R&D and from our large pool of experts outside. We give them access to free pre-clinical services from NIAID that I think Dennis might mention. And recently, we've taken a number of initiatives to help answer questions that more than one of these product developers face.

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So again, lots of support in addition to the funding.

Speaker: Ghada Zoubiane, PhD***Head of Partnerships and Stakeholder Engagement, ICARS***

It's really great to hear some of the stories, how some of these companies have progressed from one project to another or progressed within the project and really managed to achieve and really nice to hear that CARB-X is providing more than just funding.

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They're more than just funders. They're walking the path with many of these companies. So it's really something really to praise. Of course, like all the companies listening now and all of those potential interested in CARB-X, the question is: When is the next funding round? And what would the scope be for CARB-X?

Webinar Transcript**Antimicrobial Resistance: CARB-X Partners Addressing a Global Health Threat**

Speaker: Kevin Outterson
Executive Director, CARB-X
Professor of Law, Boston University

CARB-X will be making proposals on rounds that after approval by our governance will be able to make some announcements about that. The way that we typically do announcements is that we have to design specifically what it is we're looking for.

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And in the early days of CARB-X, it was like, bring us anything. We want to see everything, right. Now we have six years of experience and a significant portfolio. We'll be looking more to fill in gaps in our portfolio and to respond to the highest unmet medical needs that are not being currently addressed. So it's unlikely to be an all-comers, anything counts sort of round. It's going to be more targeted. We'll make an announcement. We'll give people a significant amount of time in order to get ready for the expressions of interest.

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We're trying to simplify the system in the program a little bit, so that it's not quite as long and as complex. And we've been working on that simplification for some time.

Speaker: Ghada Zoubiane, PhD
Head of Partnerships and Stakeholder Engagement, ICARS

Tim, I'd like to turn to you as Wellcome is one of the main funders for CARB-X, and we do know that the product development path is very difficult for many companies. And what are, in your opinion the options and the opportunities that companies have after they graduate from CARB-X.

Timothy Jinks, PhD
Head, Infectious Disease Interventions, Wellcome

The fact is, the antibiotic pipeline is insufficient to meet the world's needs. And although we're here celebrating the success of further funding for CARB-X, on the back of the successful five years, it's not just about what happens at the stage of R&D that CARB-X supports.

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But all the way through the R&D ecosystem, through the late-stage development and into hopefully market entry and deployment into health care systems. The fact is, with the market failure, there is not an attractive investment case in this space, even with CARB-X funding here. There are very few options to support the late-stage product development. Fortunately, that's changed a little bit over the course of recent time. Kevin's already mentioned that GARDP is one

entity that does support the late-stage product development for some of the antibacterial that are of global health interest.

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But in addition to that, we recently have seen come on board the AMR Action Fund. And this is an investment fund that was developed as a partnership from the private sector, the pharmaceutical industry, and in partnership with Wellcome, the European Investment Bank and WHO. So this is an additional option on top of the really very few options. BARDA is the other major player in this space with their Antimicrobial Medical Countermeasure program. This is good. What has happened with CARB-X is good. But the fact is, it isn't enough.

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What we do need to see is a change in the situation that actually invites in the private capital into this space again, makes it an attractive space for private capital. What that means is that governments have to act to change the business prospects for the products when the products do emerge here.

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And we've seen in the UK, the NHS subscription trial has now moved into implementation. And that is a model to create a pull funding mechanism. It changes the way that antibiotics are bought and are supplied into health care. It addresses important issues of delinkage. In the United States, there is a draft legislation in the PASTEUR Act that proposes an American version of a subscription model, a pull mechanism. The world needs governments to act in ways that fix this broken market. So we have progress in some ways. There are some avenues that will bring forward the most promising graduates from CARB-X.

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But frankly, it's not enough. And I hate to bring in a bit of black clouds into this event today. We're in a better place than we were. This is progress. But much, much more does need to happen, so that we can have a sustainable pipeline to meet the world's needs over the long term.

Speaker: Ghada Zoubiane, PhD

Head of Partnerships and Stakeholder Engagement, ICARS

The government needs to move, indeed. And I'm turning to you, Cameron.

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BARDA has just released their strategic plan. Would you be able to elaborate more on this strategy and the advanced research and development activities?

Webinar Transcript**Antimicrobial Resistance: CARB-X Partners Addressing a Global Health Threat**

Speaker: Cameron Bess, PhD

Project Officer, BARDA

Yeah, thanks Ghada.

It's definitely been a busy couple of weeks here at BARDA. We relaunched our partnership at CARB-X as well as our updated strategy. And as we heard from that really excellent video at the beginning, antibacterial products play a critical role in improving outcomes in health care settings.

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At the same time, antibacterial also ensure that our first responders can effectively address public health emergencies and biothreats. So at BARDA, we recognize the development space is challenging for antibacterial, and we understand that the global threat of antimicrobial resistance infection, it's global. that's why we've structured

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our antibacterials program to really reduce those barriers that drug development and drug companies face. We use a public-private partnership to provide non-dilutive funding and subject matter expertise. Our goal is to provide clinicians with therapeutics to prevent and treat biological threat agent infections, antibiotic-resistant secondary infections, as well as hospital-associated and community-acquired infections. So I will try to invoke my best

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Director Gary Disbrow, you heard in the starting video. BARDA has established unique public-private partnerships to develop antibacterial since 2010. These partnerships are focused on developing new technologies, first-in-class antibiotics, antimicrobials and diagnostics to really help save the lives of patients with AMR infections and to help reduce AMR.

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Our antibacterial program has invested over \$1.6B into this portfolio with partners coming with their own cost share of over \$5B. So what has that gotten us? We have 18 products from 14 companies are in advanced research stages now. Specifically, we have seven in Phase 3, one in Phase 2 and five in Phase 1, as well as one project in our Project BioShield initiative. In total, BARDA has funded 125 antibacterial products. We're especially proud of having helped bring three new antibiotics to market, starting with the FDA-approved VABOMERE in 2017, followed by the approval of ZEMDRI and XERAVA in 2018.

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So with seven candidates currently in Phase 3 clinical trials, we anticipate additional FDA approvals on the not so distant horizon, which we're really excited about. So again, the importance of this public-private partnership is highlighted in our US National Action Plan for CARB. Some of those, I have said before, are prioritized by first-in-class compounds, agents on the CDC's priority threats list, pneumonia, bloodstream infections, pediatrics, things formulated for oral consumption. And a really great thing we do here at BARDA is we actually support

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some of the post-marketing commitments required by companies. So again, BARDA is committed to combating AMR in alliance with our newly-launched 2022-2026 BARDA Strategic Plan. And you can read all about that and everything that we're doing at BARDA by going to www.MedicalCountermeasures.gov

***Speaker: Ghada Zoubiane, PhD
Head of Partnerships and Stakeholder Engagement, ICARS***

Thank you, Cameron.

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Really great to see BARDA's continuous support for this area. I know that Dr. Dennis Dixon was hoping to be with us, but he recorded a message that we would like to share with you today regarding NIAID's strategy, and plans and contributions. So maybe we could try to play this video now.

***Speaker: Dennis Dixon, PhD
Chief, Bacteriology and Mycology, NIAID***

NIAID is pleased to join our federal partner, BARDA, and our external partners in the new version of CARB-X that grew out of the CARB National Action Plan as a specified activity.

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NIAID will continue to provide access to our suite of pre-clinical contract services to facilitate product development for CARB-X awardees who wish to use them. In fact, nearly half of CARB-X awardees who accessed our pre-clinical services have received other forms of NIAID funding. This partnership nicely exemplifies one of the many interactions we at NIH / NIAID have with BARDA as we work together to help advance research from basic discovery to products for the public. NIH is the largest public funder of biomedical research in the world.

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And antibacterial resistance is one of the priority areas for NIH and NIAID. We remain focused on basic translational and clinical research on antimicrobial resistance with an ultimate goal of better diagnostics, treatments and vaccines. Our pre-clinical services provided to product developers is a relatively new mechanism added to the many traditional funding mechanisms for researchers and companies around the world.

***Speaker: Ghada Zoubiane, PhD
Head of Partnerships and Stakeholder Engagement, ICARS***

Webinar Transcript**Antimicrobial Resistance: CARB-X Partners Addressing a Global Health Threat**

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Thank you very much to Dennis for his video. I do want to turn to you, Erin. I think there were some questions regarding the Global Accelerator Network, and I wonder if you can elaborate briefly on it for those who are interested in how it works and what support it provides. This is one of the great features of support, and our Global Accelerator Network help in many different ways.

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On the pre-award side, there are groups like C-CAMP, for instance, in India who are getting the word out about CARB-X and what we support and what kinds of technologies and programs fit our remit. Many of our accelerators help with the preparation of the applications, help groups when they're coming in to do the presentation to understand how to pitch a program and how to answer a Q&A, that sort of thing. Help them in contract negotiations. So a lot to help people get into portfolio.

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Then once they're in portfolio, they offer subject matter expertise, and that really spans the breadth and depth of disciplines necessary to bring something from an idea through to a first-in-human or equivalent. They also engage in helping with regulatory strategy, clinical trial design, target product profile design and optimization—all very critical in order to take an idea and position it properly for the patients who need them.

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Then with CARB-X, on the portfolio level, they help us in the design and execution of these, what we're calling "Portfolio Acceleration Tools." So again, studies that are meant to really unlock questions for more than one product developer. And then finally community engagement through webinars and partnership on the business side as well.

Thank you, Erin. I wonder if I can squeeze in one more question before I hand it back to Kevin. I'm going to turn to you, Tim.

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Because you know, the latest GRAM study has shown that although we are all suffering from AMR, some people are suffering more than others.

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And when it comes to low- and middle-income countries, the burden is high. Burden of lack of access to antibiotics and innovation, but as well burden of the fact that in many countries there is unnecessary use of antibiotics.

Webinar Transcript**Antimicrobial Resistance: CARB-X Partners Addressing a Global Health Threat**

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So I wonder if you can reflect slightly on that access versus stewardship dilemma that many people keep on raising. And what can CARB-X, in your opinion, from a Wellcome perspective, deliver to low- and middle-income countries?

Timothy Jinks, PhD***Head, Infectious Disease Interventions, Wellcome*****00:28:57.480**

First of all, access and stewardship is a false dichotomy. That is something that we need to as a group around the development of these life-saving drugs, we need to make sure that it's understood that stewardship is actually a key component for making sure the best possible access can be achieved, and not set these ideas at odds with each other. But in the context of CARB-X, there's something that we've done which was relatively novel at the time.

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It was very challenging, not quite as revolutionary as one might hope. But we are providing guidance for development of stewardship and access plans to product developers.

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Because the expectation is that product developers need to design in to their development plans, and particularly in the commercialization market entry plans, the understanding of what needs to happen to both achieve access on a global basis as well as have the appropriate stewardship tools in place.

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So this is something that is fundamentally important overall to start early in thinking about what needs to be done and start putting into place the necessary things so that when those very few candidates are successful and arrive in the marketplace, that they can become available more broadly as soon as possible so that access is increased.

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And also critically, the appropriate stewardship practices can be deployed around those, so that they remain usable for the longest period of time. Thank you very much, Tim. And I will hand over to you now, Kevin.

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Thank you very much to all the panelists for answering the questions. Tim talked about the AMR Action Fund. And we are grateful that there's a private investor with more than \$1B to invest.

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Webinar Transcript

Antimicrobial Resistance: CARB-X Partners Addressing a Global Health Threat

But I was thinking we should have been calling BARDA the AMR Action Fund for the past decade because they've invested a slightly larger amount of money over the decade in a similar way. But between the various groups that are represented, we understand at CARB-X our focus.

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We're taking this amazing science coming out of things that are funded by people like NIH and similar funders from other governments around the world.

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We're translating that into a product that is proof of human safety in Phase 1. And then we're dependent on there being development partners for Phase 2 and 3, and to get it to the market and beyond.

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And so in a sense, taking it back to what Tim said earlier, we're dependent on governments leading and changing the way we pay for the way that we buy and pay for antibiotics.

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It is a big focus of my academic work and the system that we've built here is working well, but for it to be sustainable requires that last piece, the pull incentive.

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I lead a large push incentive, and I'm telling you what the world needs is a pull incentive, following on the work in the PASTEUR Act, which is not law yet and the English NHS model, which which is being implemented and other discussions around the world.

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A lot hangs on that been successful. So I wanted to thank Ghada, and Tim, and Erin, and Cameron for your time today.

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And most importantly, for the leadership from the organizations represented here, for the way that you make this all possible. Thank you.