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ANTIBIOTIC ADVANCES

FROM NEW DRUGS 4 BAD BUGS

Public-private partnerships are addressing the major challenges of microbial drug resistance.

TEXT *by* **CHRIS TACHIBANA**

Angela Wittelsberger

IN 2016, A WOMAN in the United States died from a bacterial strain resistant to 26 antibiotics. Recently, *The Lancet* reported on a dangerously resistant strain in China. The World Health Organization says that antimicrobial resistance (AMR) is a global emergency. Countering this worrying trend is the public-private program New Drugs 4 Bad Bugs (ND4BB).

Launched in 2011, ND4BB is rooted in Nordic anti-AMR actions. Physician and drug developer John Rex cofounded ND4BB when he was an executive at AstraZeneca. Sweden, he says, provided an impetus by emphasizing AMR when the country held the European Union (EU) presidency in 2009.

ND4BB is a program of the Innovative Medicines Initiative (IMI), a partnership of the EU and the European Federation of Pharmaceutical Industries and Associations. IMI works in areas where a challenge or bottleneck hinders progress, says Angela Wittelsberger, IMI senior scientific project manager. For example, no business or science sector has overcome the biological, clinical, regulatory, and financial issues of AMR, she says, but perhaps collaborations can.

ND4BB aims to coordinate and accelerate the discovery and development of new antimicrobials. The budget is 650 million of European Commission funding and in-kind contributions such as researcher and staff time from industry partners. Direct funding may support work by small and medium-sized enterprises (SMEs) or public entities such as health departments, research institutions, or patient organizations in ND4BB partnerships. IMI is not just a funding agency, however. "We see ourselves as catalysts of change," Wittelsberger explains, "facilitating new innovative models of collaboration."

A main value of participating in diverse public-private partnerships, Wittelsberger says, is learning from each other. Small businesses experience how large companies approach R&D. Industry partners gain "innovative, nontraditional, out-of-the-box ideas" from academic and clinical researchers and patient representatives, she says.

FOUR AMR CHALLENGES

Current ND4BB projects are organized under four areas: ***TRANSLOCATION*** is overcoming a common AMR mechanism–cell defenses that eject or prevent entry of antibiotics.

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ANDERS KARLÉN

ENABLE supports collaborations of academic researchers, SMEs, and pharmaceutical companies to discover and develop new antibiotics. ***COMBACTE*** focuses on clinical aspects, for example, by creating networks of research and clinical sites – more than 600 laboratories and 800 hospitals in 42 countries so far – for development of therapies and clinical trials. ***DRIVE-AB*** homes in on the bottom line – economics – with business models to encourage antibiotic development and policies for sustainable use.

TWO ND4BB EXAMPLES

Two Uppsala University professors have been involved in ENABLE since its launch in 2014. Diarmaid Hughes, Department of Medical Biochemistry and Microbiology and Anders Karlén, Department of Medicinal Chemistry, helped develop ENABLE's unique approach. ENABLE, Karlén says, is finding attractive candidates for drugs against bacteria such as E. coli using a public-private partnership model for drug development.

ENABLE IS "LIKE A VIRTUAL PHARMA COMPANY," Hughes explains, with more than 50 full-time employees across Europe, including in Denmark, Sweden, and Finland. "ENABLE brings together people from academics, big and small pharma companies, and independent experts in drug discovery and development," says Hughes. Karlén and Hughes are both busy professors but find value in their ND4BB contributions. Hughes says, "It's an opportunity to be involved in practical good for the community and possible successful drug development."

ENABLE OFFERS R&D EXPERTISE to SMEs and researchers with promising antimicrobial compounds or programs. Approved projects gain access to resources such as chemistry, microbiology, in vitro and in vivo assays, pharmacokinetic modeling, and preliminary safety studies. So far, ENABLE has received more than 70 expressions of intent, leading to 16 projects, with five still active, having passed early reviews of efficacy, safety, and other features. SMEs and academic labs are encouraged to contact ENABLE with ideas at any stage of development. "We want new programs," Karlén says, "and we're here to help."


Diarmaid Hughes

PHOTO MIKAEL WALLERSTEDT

"ENABLE BRINGS TOGETHER PEOPLE FROM ACADEMICS, BIG AND SMALL PHARMA COMPANIES, AND INDEPENDENT EXPERTS IN DRUG DISCOVERY AND DEVELOPMENT."

DIARMAID HUGHES

DRIVE-AB ACKNOWLEDGES A fundamental issue in antibiotic development, Rex says: These drugs are unlike any others. Paradoxically, use of a newly launched antibiotic must be limited to ensure long-term effectiveness, since overuse leads to AMR. Yet we inherently rely, every day, on a variety of effective, immediately available antibiotics.

Rex uses a metaphor arising from DRIVE-AB to explain: Antibiotics are the fire extinguishers of medicine. Whether we take them or not, we use them daily by assuming they are accessible when we need them. Antibiotics have "enabling value," Rex says. Because they exist, we can safely have procedures like surgery.

POTENTIAL PARTNERS INTERESTED IN ND4BB OR OTHER IMI PROGRAMS CAN LEARN MORE AT WWW.IMI.EUROPA.EU.

WE SUPPORT HAVING fire extinguishers at the ready, Rex says, but pay for antibiotics by use. DRIVE-AB decided that only a group of scientists, clinical experts, industry representatives, policy thinkers and other stakeholders could begin to solve this challenge. The DRIVE-AB goals are defining responsible antibiotic use, determining the societal and economic value of the drugs, and applying this information to drug-development business models that reflect the value and ensure the sustainability of antibiotics.

DRIVE-AB is finishing its three-year mission. A final report is expected by early 2018. The recommendations include "push" and "pull" incentives. Pushes include grants and pipeline coordination for concerted, nonredundant global R&D on antibiotics. Pulls include rewards to bring antibiotics to market, apply them responsibly, and ensure a long-term consistent supply. DRIVE-AB determined that roughly $1-2 billion should be spent globally on these types of incentives to begin to manage our AMR crisis.

HOWEVER, REX SAYS, the real output of DRIVE-AB is the people: 100 or more who, without this partnership, might not have crossed paths. "We've spent time learning to see this issue through each others' eyes," Rex says. DRIVE-AB participants are now telling colleagues in their fields about economics, policies, and actions around antibiotic resistance.

THE FUTURE OF ND4BB

The IMI is developing new areas, Wittelsberger says, with possible opportunities within ND4BB. An example is the diagnostics sector, where IMI has brought companies, research funders, and public health organizations together to explore collaborations. The first objectives will not be new diagnostics, but addressing their value and incorporating that into reimbursement strategies. AMR will continue to be an area of IMI work, Wittelsberger says: "As long as it remains an important health threat, we'll have it high on our strategic priorities." NLS