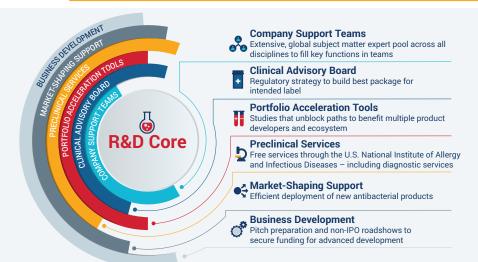






The majority of antibacterial product developers are small and micro teams, with their size making them vulnerable to costly mistakes. Taking the lead on key research and development (R&D) challenges, CARB-X created its support model to prepare developers with adequate scientific, business, and regulatory advice as they navigate the drug development pipeline. This model saves product developers time and money while advancing products more quickly to patients.



This unique, comprehensive support model accelerates individual projects as well as the entire CARB-X portfolio by connecting experts with innovators, bridging science and knowhow, and creating an ecosystem where progress meets possibility to address the global threat of dangerous drug-resistant bacteria.

With decades of diverse antibacterial R&D at its core, the CARB-X support model includes the following resources that support the evolving needs of projects as they mature.

R&D Core

The backbone of the CARB-X support model is the R&D Core, a unique team of specialized scientists and subject matter experts with decades of experience from both large and small companies. The R&D Core takes a proactive role in supporting product developers by capturing key questions of each project and its risks. Then, the R&D Core matches product developers with their Company Support Teams, comprised of expert advisors, funders, and global subject matter experts across a variety of disciplines. In addition, the R&D Core matches product developers with accelerators to maximize learning within the network. This support is essential to helping product developers reach milestones and advance their product toward the market.

"There is value to have the expertise to bounce ideas off of and to maneuver through a technically challenging program. [You] need people who understand the science, but also get small biotech, infectious disease, and risk."

Company Support Teams

CARB-X product developers are appointed dedicated Company Support Teams (CST) comprised of subject matter experts who regularly meet with developers to deliver support and oversight. CSTs are paired with developers based on their experience with preventatives, therapeutics, or diagnostics, as well as the product phase, scientific area of expertise, familiarity with the project, and geographic alignment with the product developer. Each CST collaborates with product developers to provide tailored guidance based on developers' unique proposals, project challenges, and business structures. Examples of CST support include reviewing regulatory submission documents, providing insight into toxicology reports, and assisting with identifying and working with other research organizations.

"As a tiny company, we cannot afford expensive consultants.

CARB-X does a good job of bringing in expertise (scientific, medical, business) ... Simply the availability of experts in various fields from places is absolutely wonderful."

The CARB-X Comprehensive Support Model

Clinical Advisory Board

The Clinical Advisory Board (CAB), comprised of experts with deep experience in the global clinical development of infectious disease products, monitors and advises product developers with the goal of streamlining the clinical trial process. The CAB intervenes early, working with product developers to identify what they want their label to look like, whether they have the proper documents for approval, and how to design a phase 1 study that is informative and attracts downstream investors. In addition, the CAB helps product developers create a regulatory strategy to build the best package for their intended drug label and identify regulatory hurdles and solutions for progressing products in the U.S. market for Federal Drug Administration approval as well as other markets across the globe.

"We got great feedback on how to present data and tell a compelling story. It was instrumental in succeeding through that milestone."

Portfolio Acceleration Tools

Common roadblocks face many product developers, including those in the CARB-X portfolio. To alleviate these challenges, CARB-X developed an economical series of Portfolio Acceleration Tools (PATs) that are designed to save time, energy, and money across the entire ecosystem. Each PAT is a standardized and validated model that helps members of the portfolio optimize their products and advance them more quickly to patients. By utilizing PATs, product developers gain a deeper understanding of toxicity risks, standardized animal models, antibiotic susceptibility, and the antigenic variability of global bacterial strains, among other topics. CARB-X regularly seeks new PATs to add to the portfolio by engaging product

developers to learn which tools would help them the most based on their shared experiences. Use the QR code to learn more:

"Our project started but may not have continued without the support of CARB-X."

Preclinical Services

CARB-X works with the U.S. National Institute of Allergy and Infectious Diseases (NIAID) to give product developers access to free preclinical services to support the development of therapeutics, preventatives, and diagnostics, at no cost to developers. These preclinical services include synthesis

and manufacturing support, efficacy assessment, diagnostic services such as reagent production, assay development, and pathogen sequencing, as well as nonclinical profiling including toxicology profiling and immunogenicity studies, among other services. These preclinical services streamline the development of each project toward the market.

"I initially thought that NIAID access would be lengthy and difficult. We had several collaborations with NIAID, which in fact very rapidly and efficiently solved key questions. High quality work."

Market-Shaping Support

This tool improves the ability of new products to be readily accessible by patients who need them, including those living in low- and middle-income countries (LMICs). CARB-X offers market-shaping support to coordinate with stakeholders to ensure the efficient deployment of new antibiotics and diagnostics, creating more opportunities for new products to effectively reach their target markets.

"Overall, we're very grateful for the support. It's difficult to work on a program like this with a small company without the support from CARB-X."

Business Development

🗱 CARB-X's business development support prepares product developer leadership for the fundraising required for advanced development, connecting developers with the knowhow and investors they need as they mature through the drug development pipeline. Highlights include annual events such as the CARB-X Product Developer Conference and CARB-X Investor Day. The Product Developer Conference invites all of CARB-X's active developers to collaborate and meet with CARB-X staff and leadership, funders, and other developers within their product pillar. During CARB-X Investor Day, developers in more advanced product stages are invited to present their projects to downstream investors that are interested in investing in antimicrobial products. These conferences forge opportunities across the CARB-X portfolio. creating meaningful opportunities for product developers to gain hands-on business development experience and expand their networks.

"CARB-X has helped us to start building a network ... and has been very helpful in identifying new partners."





















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