

## Stewardship and Access Plan Development Guide

# Q&A

### **What is Stewardship and Access?**

The world urgently needs new antibacterials, diagnostics and preventatives such as vaccines to counter the rise in drug-resistant infections. But simply developing these products and bringing them to market is not enough if patients do not have access to them, or if antibacterials become ineffective due to overuse. Equitable access means the product being accessible, available, affordable and acceptable for its intended use, and responsible stewardship means taking appropriate action to limit the pressures that lead to the rise in resistance, including administering antibiotics only after proper diagnosis and the selection of the right drug regimen, dose, duration and route of administration. These access and stewardship principles must exist alongside efforts to research and develop new products; so that these vital products are available to patients who need them, used responsibly, and safeguarded for future generations. This is essential to stay ahead in the global race against resistance.

### **Why is the Stewardship and Access Plan Development Guide so important?**

The Stewardship and Access Plan (SAP) Development Guide is a first. It is the world's first practical guidance on what strategies and actions product developers could adopt to meet the expectations of governments and donors and live up to the principles of stewardship and access. The Guide was developed collaboratively by a working group comprising of CARB-X, several of its funders (the United States Department of Health and Human Services (HHS) Office of Global Affairs (OGA) and Biomedical Advanced Research and Development Authority (BARDA), the UK Department of Health and Social Care (DHSC), the Bill & Melinda Gates Foundation (BMGF), and Wellcome Trust), as well as the Global Antibiotic Research and Development Partnership (GARDP) and the Access to Medicine Foundation (ATMF), with valuable consultative input from the Biotechnology Innovation Organization (BIO). This Guide therefore represents the world's first 'gold standard' benchmark for what companies can reasonably be expected to undertake in relation to stewardship and access.

### **Why was this Guide created?**

CARB-X provides non-dilutive funding and support to product developers of new therapeutics, preventatives and rapid diagnostics to prevent, diagnose and treat life-threatening antibiotic-resistant bacterial infections. CARB-X awardees are contractually obligated to develop an initial Stewardship & Access Plan as the product enters pivotal clinical trials (generally Phase III or equivalent for diagnostics), outlining what strategies they will deploy to ensure responsible stewardship and appropriate access in LMICs. This Guide was designed to assist them in fulfilling these contractual obligations. We hope that the guidance is also useful to other developers of products addressing AMR and the wider scientific, biotech/pharma and global health community.

### **How should product developers use this Guide?**

Planning for how to promote access and stewardship of a new product is the socially responsible thing to do, and should begin at the early stages of R&D. For CARB-X product developers, the Guide describes the six key areas that should be included in the SAPs they are required to develop under the terms of their funding. The Guide also includes questions companies should consider during the R&D process, and outlines examples of the strategies and policies that could be adopted. Further, the Guide includes a list of organisations that may be able to provide non-binding confidential advice and support related to access and stewardship. We hope that all product developers will find the Guide useful and take an ambitious approach to achieving equitable access and responsible stewardship of their crucial products.

### **How do these standards align with the actions of other government and industry stakeholders?**

These standards are designed to serve as a starting point to inspire all stakeholders to step up and proactively do their part to achieve sustainability and access. The Guide was developed by leading funders of antibacterial, diagnostic and vaccine development, and therefore represents the new expectation of these governments and philanthropic donors. However, responsibility does not rest with product developers alone. Greater action is needed from governments, donors and civil society, working with industry, to develop solutions that simultaneously accelerate equitable access to new products addressing resistant infections and slow down the spread of drug resistance.