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Steven C. Schachter, Wade E. Bolton  
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# Accelerating Diagnostics in a Time of Crisis

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The Response to the COVID-19 Pandemic  
and a Roadmap for Future Pandemics

Edited by

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Rapid Acceleration of Diagnostics (RADx<sup>®</sup>) Chief, CIMIT

**Wade E. Bolton**

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Dedicated to Lindley Hall for his mentorship, John Parrish for his pioneering work to accelerate health-care solutions and to Wallace and Joe Coulter and their spirit of Science Serving Humanity.

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## Foreword

Harvey V. Fineberg

A deadly pandemic demands a response at multiple levels of government and society and across myriad needs for public health and medical care. As the COVID-19 pandemic took hold in early 2020, the US response faltered. Hospitals lacked sufficient personal protective equipment for staff and, as cases surged, some were overwhelmed by sick patients. Optimal care for extremely ill patients was uncertain. The federal response lacked a clear leadership structure and chain of command. Antivirals were lacking, and an effective vaccine was yet to be developed. Moreover, the Centers for Disease Control and Prevention initially distributed a test kit with a faulty reagent, setting back the national testing strategy for COVID-19.

The nation's premier biomedical research organization, the National Institutes of Health (NIH), focused its COVID-19 efforts on three main goals of research: vaccines, therapeutics, and diagnostics. By April 2020, the NIH had activated a public-private partnership to accelerate the development of COVID-19 therapeutics and vaccines. Through funding and active collaboration, the NIH was instrumental in the development of the Moderna vaccine. With the active engagement of 20 companies and scores of scientists, the NIH screened hundreds of therapeutic candidates, embarked on clinical trials for more than three dozen of the most promising, and obtained six therapeutics approved for clinical use. Fueled by a special congressional appropriation in April 2020, the NIH launched the Rapid Acceleration of Diagnostics (RADx<sup>®</sup>) initiative. Within six months, the Food and Drug Administration granted emergency use authorization to the first point-of-care – rapid COVID-19 tests funded through RADx – and since then more than four dozen RADx-supported tests (20 point-of-care, 16 laboratory-based, and 13 home-based tests) have received emergency use authorization.

The pandemic demanded unaccustomed speed, intensity, and flexibility in research. All of the institutes of the NIH responded to these pandemic exigencies. However, RADx stands out for its degree of innovativeness and readiness to embrace non-traditional ways of doing business at the NIH.

Led by the National Institute of Biomedical Imaging and Bioengineering, RADx built on years of experience gained through CIMIT and the Point-of-Care Technology Research Network that is coordinated by CIMIT. Rather than consider the aim to be funding brilliant research, RADx adopted an outcomes-oriented approach that embraced every stage, from scientific idea through proof of concept, product development, manufacturing, clinical evaluation, regulatory review, and authorization for use. Rather than traditional peer review, RADx developed a shark-tank approach of presentation, assessment of promise, and investment, followed by an innovation funnel with development milestones and sequential winnowing or intensifying investment. Rather than a hands-off approach after grant approval, RADx adopted venture-capital-like continued support and coaching to overcome any obstacles along the way.

These innovations meant that RADx would seek and foster ideas that had the promise of success and not simply look for reasons that a project might fail. Thus, RADx did not accept an inevitable “valley of death” for biomedical product development; RADx established oases of support that carried easier-to-use, faster, and more reliable diagnostic tests from scientific

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ideas to clinical laboratories, sites of clinical care, and homes. Because of RADx, as many as 3 billion COVID-19 tests have entered the US market, and rapid home and point-of-care tests have become the norm.

This book describes the concept, organization, implementation, and results of the RADx initiative. It provides many cases to illustrate the varied ways that the RADx model, combining the best of public and private capacities, contributed to the success. It shows how RADx adapted and learned from failures in real time to strengthen its approach. The book positions the quest for more and better diagnostic tests – accurate, easy to use, and widely available – against the backdrop of multiple pandemic demands on clinical care and public health. The RADx experience holds lessons not only for the development of future diagnostics but also for any situation in which multiple scientific scenarios may yield technologies to help meet an urgent health need.

More than three years after the start of COVID-19, the United States and much of the world appear to have weathered the brunt of the pandemic, although the toll on lives and the financial impact continue to mount, and post-acute sequelae of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) remain an ongoing clinical dilemma. China, whose zero-tolerance policies held off the full force of COVID-19 for a couple of years, has since found itself in the throes of the pandemic and has lent its weight to the growing, global burden of disease.

With time, we can anticipate many assessments of the pandemic response at the global, national, and subnational levels. Many will proffer lessons, and some will be worth heeding. The RADx story told here meets that high standard, worthy of heeding, in preparing for the next pandemic or for any similarly severe and urgent health threat.

# Preface

Wade E. Bolton

In 2019, a unique virus emerged on the world scene that would cause a global affront to our health-care systems. Hundreds of millions of individuals became infected with the virus, resulting in millions of lives lost and catastrophic financial damage. In the United States alone, the pandemic was the most significant medical calamity in the history of our nation, surpassing the lives lost in World War I and World War II combined and even outnumbering the casualties of the 1918 Spanish flu pandemic. As a member of the coronavirus family, which was later named SARS-CoV-2, this raging virus at first appeared to resemble two of its predecessors, SARS and Middle East respiratory syndrome (MERS). The scientific community soon learned, however, that the differences among them were stark.

Through the NIH's RADx initiative, a network of professionals was established to respond to the virus through the development and distribution of diagnostic tests that could accurately diagnose the presence of the virus in patient samples. Our assignment had no boundaries. We reached across international borders, collaborated with the brave men and women in the field, and were welcomed by academic and government institutions willing and able to join in the fight against this common foe. We understood that this was our absolute priority – a national and global mandate with millions of lives at stake.

This book documents how the limits of science and discovery were pushed in a collective effort to contain and manage this pandemic, from the development of diagnostic assays to the surveillance of and response to emerging variants. The authors describe what was done differently to identify, develop, and distribute diagnostic tests in record time and volume. We provide the framework for technical, organizational, practical, and operational action items that are essential to the management of an emergency health crisis. We describe our lessons learned and what we would have done differently to improve the outcomes. And, critically, each chapter includes a roadmap that details the steps necessary to optimally respond to the pandemic. (For a complete roadmap comprising all of the action steps plotted over time, readers will be able to turn to our website, [pandemicresponseroadmap.org](https://pandemicresponseroadmap.org), once it is live.) We believe this collection of roadmaps is the first comprehensive response plan based on real-life pandemic experiences.

The publication of this book is timely, as the impact of COVID-19 is currently undergoing overall evaluation. We are hopeful that the experiences, roadmaps, approaches, and frameworks herein will serve as scaffolding upon which our colleagues can build when they begin to plan their response to the next health crisis.

## The Website

The [pandemicresponseroadmap.org](https://pandemicresponseroadmap.org) website will offer a valuable resource for individuals seeking to enhance their understanding of pandemic response strategies. Through an interactive and customizable pandemic response roadmap, users will be able to gain insights into the complex and evolving nature of pandemics and develop customized strategies to navigate them effectively. Our author biosketches will provide detailed accounts of the training and experiences of each author, enabling readers to trust in and appreciate their

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unique perspectives and expertise. Additionally, our compiled list of lessons learned during the COVID-19 pandemic will offer insights into successful pandemic response strategies and areas for improvement. By leveraging the collective knowledge and experiences of our authors, our website aims to expand upon the knowledge provided within the book pages to further contribute to a more informed and effective global pandemic response.

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