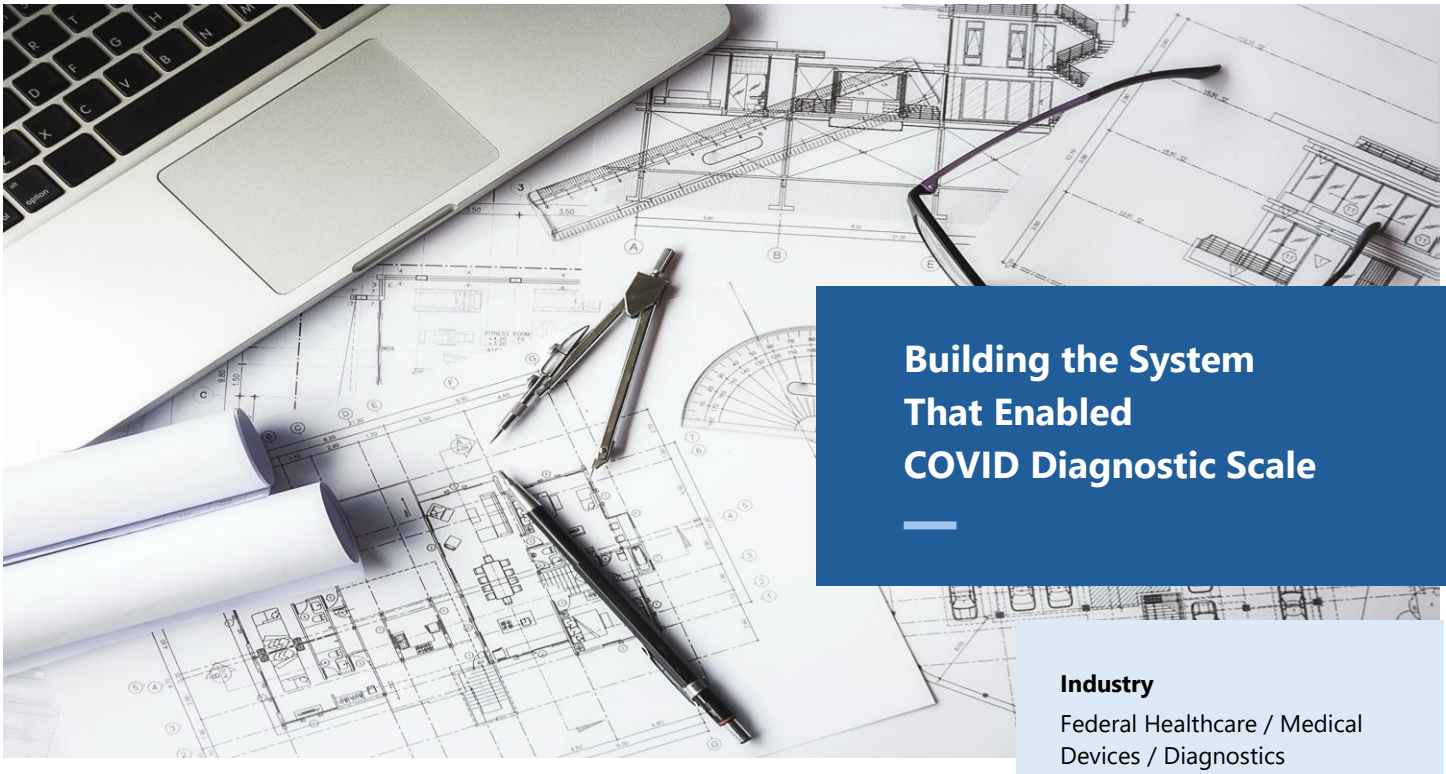
CASE
STUDY

SHOREFRONT STRATEGIES LLC



Building the System That Enabled COVID Diagnostic Scale

Industry

Federal Healthcare / Medical Devices / Diagnostics

Notable Results

- Enabled commercialization and scale-up to **50M+ COVID diagnostic devices deployed**,
- Grant awards $3M to $40M.
- Reduced time-to-market from **18–24 months to 8–9 months**.
- Recipient of the **RADx Fellow Award for Outstanding Contributions**.

AT A GLANCE

The problem was not a lack of ideas. It was getting those ideas to scale.

In 2020, the U.S. needed diagnostic capacity quickly. The NIH RADx program brought together scientists, diagnostic companies, NIH leadership, and FDA. Each group understood their part of the problem, but there was no shared way to move from concept to production in a reliable way.

I worked across that system to help align it and make it executable. The focus was not on any single technology. It was on creating a path that could consistently take multiple technologies from early promise to real production.

As a Commercialization Program Manager, I helped align these groups and introduce **structured execution**, enabling technologies to move from concept to scalable, regulatory-compliant products.

My engineering and automotive background introduced a critical element:

Standard work—applied to commercialization under crisis conditions.

CLIENT'S GOALS

The ultimate client was the **American public**—individuals, healthcare providers, and communities relying on accurate, timely diagnostics during a rapidly evolving pandemic.

That meant moving viable technologies forward without unnecessary delay, meeting FDA expectations the first time, and building manufacturing systems capable of producing millions of tests per month. It also meant maintaining accuracy as the virus evolved and ensuring testing was broadly accessible.

Success required building a system capable of delivering reliable, scalable diagnostics—fast enough to matter.

THE CHALLENGE

Most teams involved were strong in one area, but not across the full system. Some had solid science. Others understood regulatory pathways. Others had manufacturing capability. Very few were aligned across all three.

At the same time, technologies were at different levels of maturity, regulatory expectations were evolving, and supply chains were under pressure. The timeline added another layer of complexity.

The process for FDA approval was also long and costly. Without a clear path, teams often moved slowly, repeated work, or missed expectations late in the process.

A key part of making the system work was establishing a standard workflow for approval. That created a clearer path forward and reduced uncertainty across teams..

THE APPROACH

We established a clear path from concept through approval and scale using a staged approach. WP0, WP1, and WP2 created defined steps with clear expectations and decision points. This gave teams a shared framework to work within and removed a lot of ambiguity.

At the same time, I worked across scientists, companies, NIH, and FDA to keep decisions grounded in both technical reality and execution readiness. The goal was to make sure progress reflected what was ready, not what was assumed to be ready.

A big part of the work was identifying and resolving risk early. That included gaps in regulatory strategy, manufacturing readiness, and supply chain capability before programs advanced. It also extended beyond launch. I led testing of on-market assays against emerging COVID variants to confirm that performance held as conditions changed.

The focus was not just on moving faster. It was on moving forward with fewer surprises.

THE RESULT

More than 50 million diagnostic devices were deployed across the United States, with multiple programs reaching production levels of 10 million units per month.

Time-to-market was reduced by more than half, and coordination across science, regulatory, and manufacturing improved significantly.

What matters most is that the system held up under pressure. It worked not just once, but across multiple programs moving at the same time.

ACHIEVEMENTS

- Led execution across NIH, FDA, and industry
- Introduced standard work into a non-linear environment
- Helped align scientific, regulatory, and operational teams
- Led national variant validation coordination
- Managed $1M–$40M federal programs
- RADx Fellow Award Recipient
- Contributor to *Accelerating Diagnostics in a Time of Crisis* (Cambridge University Press, 2024)

EXPERTISE ALONE DOESN'T SCALE.
STRUCTURE DOES.

Let's Connect

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