Pro-QCP™: A Product You Have to Love

Bill Donohue, President/CEO CarePoint Solutions
11/11/2020

I have a track-record of bringing ground-breaking innovative products to the diagnostics market, but Pro-QCP is by far the most exciting product I've championed in my 38-year career. Pro-QCP is a web app that helps clinical labs comply with new federal quality assurance requirements, gives clinicians the actionable data they need to ensure diagnostic test accuracy, implements a process for continuous quality improvement, and provides valuable industry-wide performance data, all for the first time.

During alpha-testing, labs that used Pro-QCP to satisfy new federal requirements to produce Individualized Quality Control Plans produced superior QC plans and reported increased confidence in the accuracy of the patient test results they report. We have succeeded at scaling our novel approach and are now preparing the commercial launch of Pro-QCP, in over 300 different modules, each specific to a different mainstream diagnostic test. Of those 300 initial modules, 150 will be focused on Covid-19 diagnostic platforms.

It is important to know that most diagnostic errors are not related to the analyzer or the test kit, but rather to the non-analytical aspects of the testing process (e.g., specimen collection, specimen transport, patient identification, timely delivery of results, etc.) Pro-QCP is the first software app to guide clinicians through a comprehensive risk assessment, specific to each test lab and collection station, to identify and address sources of error. Pro-QCP considers variables relative to environment, personnel, methods employed, procedures that are in place, and the needs of the patient population being served. The web app also provides inter-laboratory comparison reports that establish performance benchmarks and allow users to compare their performance to that of their peers.

Medical Laboratory Techs (Med Techs) love Pro-QCP because it provides step-by-step guidance through a murky and cumbersome regulatory compliance process. Most Med Techs have not had formal training in risk mitigation so our guidance is needed and appreciated, and the efficiency of our process saves them a ton of time. A clinical study published by one of Pro-QCP's alpha-testers, Baptist Medical Center in Memphis, concluded that Pro-QCP not only produced a superior quality control plan,

William Donohue, President
CarePoint Solutions, Inc.   100 Cummings Center   Suite 434-E   Beverly, MA 01915
bill.donohue@carepointsolutions.com   508-517-6849

but it saved them 50 hours of labor when conducting their risk assessment. This means Pro-QCP's $795 annual subscription fee can be recovered almost immediately in time savings alone. When Lab Techs are onboarding new diagnostic tests for the first time, Pro-QCP is particularly valuable as it moves them up the learning curve quickly and ensures an effective quality control plan right from the start. Pro-QCP then delivers the documentation labs need to satisfy regulatory compliance and help ensure successful federal inspections.

Regulatory Affairs managers that oversee large healthcare delivery networks love Pro-QCP because the program standardizes what is now a haphazard process across their system. They typically have regulatory compliance responsibility for a myriad of lab locations and test platforms. By standardizing QA procedures across the board with Pro-QCP, our program gives them assurance that each of their labs has implemented a federally-compliant quality management process and is ready for their next inspection. Also appreciated by Regulatory folks is that Pro-QCP represents a 'turn-key' solution for hospitals seeking to fulfill JCAHO and other accreditation agency requirements that call for the implementation of new quality improvement initiatives.

Now that federal Medicare reimbursements are being factored more and more on patient outcomes, hospital CEO's love Pro-QCP because of the program's potential to improve clinical outcomes, increase Medicare reimbursements, prevent adverse events and fatalities, reduce the number of malpractice law suits, lower insurance premiums, drive efficiencies throughout their healthcare system, and improve their organization's bottom line.

Even federal inspectors love Pro-QCP. Inspectors know that if a lab has undergone Pro-QCP's comprehensive risk assessment, all of the underlying regulatory requirements have been satisfied. This saves them time and effort during their audit, and Pro-QCP becomes a de facto 'certificate of compliance' for our end users. We have received requests from Health & Human Services inspectors for Pro-QCP brochures, so they can distribute them to the majority of labs that they inspect that are still falling short in meeting the new federal quality standards. These inspectors will be our best sales reps!

I mentioned how Pro-QCP implements an innovative new process for continuous quality improvement. Pro-QCP supports a culture of quality by monitoring key performance indicators via dashboards, providing performance alerts, engaging front line care-givers in the quality assessment, and recommending proven risk

mitigation practices that can be 'data-mined' from our community of users... all for the first time.

And if that isn't enough, Pro-QCP will become the first world-wide, real-time diagnostics test surveillance system. The value of this can't be understated as we will be advancing the world's first means to monitor the performance of each diagnostic platform, as used in real world conditions, in real time. Based upon the data we will collect, own, and publish, we will be in a position to establish performance benchmarks and flag poorly performing test platforms that pose the greatest threat of harm to patients and to the public. This is of immense value to society, to federal oversite agencies, to hospital and laboratory accreditation agencies, and to the clinical lab community at large. It is also essential information for every lab director about to make a purchasing decision regarding the most appropriate and reliable diagnostic tests for their lab and the patient populations they serve.

But let's talk specifically about Covid, and Pro-QCP's potential role in the pandemic. Covid testing has been called a perfect storm for diagnostic error, and it's easy to see why. Hundreds of new, minimally validated diagnostic tests are flooding the market, novel technologies are being applied to Covid testing for the first time, hundreds of thousands of collection sites and point-of-care test locations are popping up all over, and just about every clinical lab is onboarding new Covid tests for the very first time.

Unfortunately, with this rush of unproven diagnostic tests to market, human beings are 'guinea pigs' and real-world performance data are being collected for the first time. Even as we gain valuable experience from the front lines, we are not learning from it. Those critical performance data are sitting in silos – healthcare system information systems across the country – and are not being shared or leveraged for the greater good. If you are a lab director, with responsibility for the accuracy of the tests that you purchase and manage, think of how valuable it would be to compare your lab's performance to hundreds of other labs performing the same test. Or to know which test platforms perform well and which ones don't. Pro-QCP captures, aggregates and analyzes those data for the first time, so we can gain a macro view of the market and determine not only how each *lab* is performing as compared to its peers, but how well each Covid *test platform* is performing.

With Covid testing, because false negatives and false positives can directly result in fatalities, the moral and ethical imperative to ensure diagnostic accuracy is great. Reliability of tests is also critical to protecting our front-line caregivers and essential

William Donohue, President
CarePoint Solutions, Inc.   100 Cummings Center   Suite 434-E   Beverly, MA 01915
bill.donohue@carepointsolutions.com   508-517-6849

workers, and ensuring the efficacy of contact tracing efforts. With so much riding on these test results, it can be argued that any and all efforts that can be taken to improve accuracy and reliability are warranted.

Strategically speaking, this is a historically unprecedented opportunity and CarePoint is in a unique position to respond. By claiming our role in battling the world-wide pandemic, CarePoint will have the potential to get our product placed in just about every clinical lab, worldwide. I don't know many products that can make that claim. My favorite Carl Sandburg quote is "In times of a gold rush, it's good to be in the pick and shovel business." As point-of-care testing for Covid expands into drive-thru clinics, mobile labs, employer-based screening programs, and potentially to every grocery store and pharmacy, the number of new test labs and collection sites will continue to explode, and so too will be the incidence of diagnostic errors, and the need to prevent them.

Once we do our 'magic' to improve Covid testing, we will be poised to do the same for the balance of the $80B clinical diagnostic market, upselling Pro-QCP modules for other test methods that our subscribers employ. A typical hospital has 8-10 test methods that would benefit from a Pro-QCP risk assessment, representing over $7k in annual subscription fees. This average will only increase as we expand our offering.

In summary, Pro-QCP has the potential to fill a huge market vacuum, become an industry standard, be the sentry for monitoring diagnostic performance, and save hundreds of thousands of lives. It is being launched precisely at the right time to play a critical role in the effort to contain Covid. As a first-mover, we plan to take an early lead in this newly emerging niche market and then *own it*. We will do this by continuously evolving and innovating our product, offering more and more features and value over time, and grabbing as much market share as we can, ahead of any competition. And as our user base grows, the value of Pro-QCP's inter-laboratory comparisons will increase. This also means that as we build a large community of users, we will achieve a 'critical mass' that new market entrants and competitors will be pressed to match. We are also excited about several parallel niche markets and other healthcare applications for which the Pro-QCP platform appears to be ideally suited.

As the company's CEO, I believe CarePoint's success will only be limited by the creativity and effectiveness of our marketing and how quickly we can respond to the market demand. Our marketing strategy focuses on partnering with major players in

William Donohue, President
CarePoint Solutions, Inc.   100 Cummings Center   Suite 434-E   Beverly, MA 01915
bill.donohue@carepointsolutions.com   508-517-6849

the diagnostic industry that can deliver huge audiences and help us penetrate into every segment of the market. We are building an elegant partner referral system employing a coupon promotion that feeds directly into the Pro-QCP commercial front-end to facilitate and manage incoming business from our strategic partners. And you will be glad to know that we have built Pro-QCP to be exponentially scalable, right from the start.

The most profitable and fastest growing companies these days are 'product driven companies.' These companies are built on products that 'sell themselves' and go viral. (Viral in a good way!) I would propose that Pro-QCP has *all* the attributes of a viral product: software-as-a-service, easy to promote, easy to refer, easy to co-market with industry leaders, intuitive to use, requires minimal support, fully scalable to meet market demand, subscription-based model providing reoccurring revenues, first-of-it's-kind product with no apparent competition, fills a specialized/niche market need, has a large market potential, and offers a compelling value proposition. When we did a brief market test of the alpha-version of Pro-QCP, about a third of new subscribers purchased the program from our website without any personal contact from CarePoint. This confirms that our value prop is strong, our marketing communications are effective, and that our customer acquisition cost going forward should be very low. And since most of our costs are in building the program, we will be operating at close to a 100% gross profit. That's what I call printing money.

In conclusion, I'd like to suggest that CarePoint's stockholders will love Pro-QCP the most. Especially when Pro-QCP revenues start to deliver the 'other-worldly' earnings that we are anticipating.

Thanks for being part of this collaboration, for supporting the important work we are doing, and for making this opportunity possible.

William Donohue, President
CarePoint Solutions, Inc. 100 Cummings Center Suite 434-E Beverly, MA 01915
bill.donohue@carepointsolutions.com 508-517-6849