COVID-19 Transforms IVD Industry From Concept To Market

The emergence of COVID-19 forced rapid change within the In Vitro Diagnostics (IVD) industry. Approximately three months passed between the first notification of SARS CoV-2 in Wuhan in December 2019 and the WHO classification of COVID-19 as a pandemic in mid-March 2020.

With the rapid transmission of the virus, the need for tools to quickly diagnose infection became critical, and with that an industry that has long struggled to be perceived as more than a commodity, became a household name and front and center of leadership discussions at the highest level in government.

Very quickly, IVD manufacturers were pressured to help facilitate ramp up of testing capacity across the globe and help build out existing and new channels for testing. The circumstances of the pandemic forced companies to reallocate investments in R&D, production processes, and supply chain management, while having to critically assess traditional commercial models. Ultimately, companies were pressured to innovate their entire operational model from concept to market. This disruption will impact the industry well beyond 2020 and drive permanent change in how companies orchestrate across business processes to thrive.

R&D DISRUPTION DURING COVID-19

The pandemic provided stimulus for innovation across multiple functional pillars, initially with pressure to drive swift R&D, followed by the ability to rapidly increase manufacturing speed and scale.

COVID-19 Test Development And Production

Transparent communication with health organizations and sharing of information such as the genomic sequence of the SARS CoV-2 virus were critical in the industry's ability to respond globally. Still, industry remains under pressure to adequately support the global healthcare infrastructure in the management of the pandemic.

Within weeks, IVD manufacturers needed to refocus their R&D expertise and resources to develop high-quality COVID-19 tests. What often takes two to three years, had to be achieved within one to two months, putting IVD manufacturers, OEMs, and laboratories to the test.

FDA responded quickly by providing guidance on Emergency Use Authorization approval for SARS CoV-2 tests and by mid-March the first commercially produced test received EUA approval in the U.S.[1] Since then, more than 250 tests have been cleared for temporary commercialization in the U.S. under EUA.[2] More and more companies will seek to transition to full 510k clearance in 2021, but many will not make this changeover once EUA is lifted. This will require collaboration with a competent CRO that has experience in collecting data pre and post commercialization to minimize costs and facilitate a timely and smooth transition.

Despite clearance, volume remains an issue. The IVD industry typically does not operate with excess manufacturing capacity. To ramp up test volume, investments in new manufacturing and production facilities need to be made, but those take planning and time. OEM partners quickly saw requests for equipment and machinery to help with the aggressive assembly and production of needed supplies. Development cycles were pressured to produce materials and equipment in less than half the normal cycle time.

Now, more than six months later, companies have benefited from government funds made available to increase COVID-19 testing capacity. In total, more than 20 diagnostic companies have received U.S. BARDA funding to scale up manufacturing; total BARDA funding to diagnostic companies has exceeded $60 million.[3] Still, as of September 2020, 30% of laboratories interviewed in a recent IQVIA survey reported COVID-19 testing capacity falling below testing needs.[4]

Learnings from delivering in line with such aggressive development and commercialization timelines will last beyond 2020 and include the effective utilization of CROs that can facilitate orchestration across critical functional pillars and ensure that the standards stipulated to obtain BARDA funding are met.

The Need For Data Integration

Data integration, connectivity, and analytics will also need to remain at the forefront of innovation in 2021.

Today, transmission of data remains problematic. The integration of data into various types of electronic systems and into a patient's electronic health record remain elusive goals. The COVID-19 pandemic highlighted the ongoing challenges in coordinating patients' results across multiple channels and testing entities.

Identifying solutions to the ongoing interoperability of data and electronic medical records will see much attention and investment in 2021. In light of reduced facility access, remote instrument performance monitoring and maintenance tools, as part of software and middleware solutions will also gain additional relevance in 2021 and beyond.

With some of the financing and investments laboratories have received as part of the COVID-19 pandemic, some larger CAPEX projects are being considered and are expected to get attention in 2021, including some of the more challenging projects around data integration. In a recent study, 72% of laboratories referenced an increase in their 2021 budget as a result of COVID-19.[4]

IVD manufacturers who can bring meaningful change through partnerships or internal competencies in the area of data integration will see demand for such offerings increase in 2021.

MANAGING SUPPLY CHAINS

Shortages of testing supplies were and continue to be widespread. Industry was unprepared to address the rapid change in laboratory demands for test kits and supplies. Laboratories were ill prepared with in part outdated testing equipment. Demand for raw materials needed for instrumentation more than doubled shortly following the onset of the pandemic. Laboratories, OEMs, and large IVD manufacturers increased staff to manually assemble products because of delays in receiving automated equipment. According to a recent IQVIA survey, laboratories invested on average nearly 11% more in instrumentation since the start of the pandemic and increased staff by approximately 8% to address bottlenecks.[4]

An overdependence on select suppliers and their geography during times of aggressive demand, led to supply shortages and sample backlogs. Laboratories specifically called out shortages of viral transport media, swabs, reagents, and tubes; shortages that still remain in part today.[4]

Going forward, IVD manufacturers will look to de-risk supply management, minimize overdependence and carefully reevaluate the geography of the supply chain with the goal to spread out bottlenecks and address potentially challenging cross-border logistics. In parallel, laboratories will diversify their instrumentation to become less reliant on a single test provider and platform. Implementing and preparing for these changes in industry and at the customer level will be key in 2021.

THE ERA OF A NEW COMMERCIAL MODEL

The wide-ranging disruptions stemming from the COVID-19 pandemic are also expected to permanently change broader interaction and go-to-market models. IVD manufacturers needed to be flexible and creative in supporting their customers, the laboratories, in setting up testing capabilities efficiently and rapidly in an environment where face-to-face interactions were challenged.

With an investment focus on equipment and aggressive test and instrument production, IVD manufacturers have begun to recognize the need to change the traditional commercial model. Funds traditionally used for conferences and roadshows are now being used for webinars and virtual events. Sales reps are increasingly interacting with their customers remotely because of limited access to facilities. In the U.S. alone, remote rep interactions have increased by close to 400% compared to pre-COVID levels.[5] While rates may settle, establishing a successful remote engagement system will be essential and a consistent component of a successful commercial model in the future.

Less established companies who have been aiding in the development of COVID-19 tests are needed to address unmet needs. However, many lack the resources to invest in sales teams. Transitioning, even temporarily, toward a highly skilled and trained contract sales force would provide manageable opportunities. Given the uncertain environment, this model is expected to be adopted more frequently in 2021 and beyond, to provide flexibility and responsiveness to quickly changing market conditions, while managing capital and staying in control.

CONCLUSION

Orchestrating seamlessly across functional pillars will be critical in 2021. As uncertainty remains, such orchestration will be required to ensure rapid commercialization of quality tests and data management solutions, while remaining flexible and implementing a cost-effective, innovative commercial model. Laboratories will seek to invest based on funds that were received during the pandemic. IVD manufactures need to be able to respond quickly with commercial development and execution. To achieve this entails taking a business process view of the full IVD product life cycle, from concept to market, and bringing together the technology, products, services, consulting, data, and technology-enabled managed services necessary to combine each link in the value chain. In practice, these changes will require IVD companies to use the collective resources and industry experience they possess and that of their trusted partners. Companies that make this transformation will be best positioned to emerge from these times of change in a position of strength.

REFERENCES

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