

# Insights Series

Issue 14  
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expanding-precision-medicine

The New Normal



## Precision diagnosis in the COVID-19 era and beyond

A thought leadership paper on how to improve diagnostic accuracy

# Preface

## The Insights Series

The Siemens Healthineers *Insights Series* is our preeminent thought leadership platform, drawing on the knowledge and experience of some of the world's most respected healthcare leaders and innovators. The Series explores emerging issues and provides you with practical solutions to today's most pressing healthcare challenges.

We believe that increasing value in healthcare – delivering better outcomes at lower cost – rests on four strategies. These four principles serve as the cornerstones of the *Insights Series*.



Our *Insights* portfolio is an integrated collection of events, speaking engagements, roundtable discussions, and an expanding array of print and digital platforms and products all carefully curated to share ideas, encourage discussion, disseminate original research and reinforce our position as a healthcare thought leader.

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# Executive summary

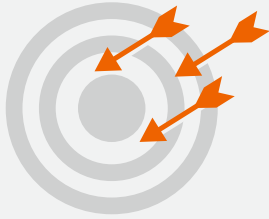
**The COVID-19 pandemic has brought an intense focus on diagnostics, highlighting the relevance of accurate and timely diagnosis for increasing the quality of care and reducing healthcare- and community-related costs.**

The pandemic has exposed four key factors that limit the ability to make precise, data-driven diagnoses: low-quality data, non-comprehensive data “snapshots”, non-actionable information, and a siloed approach.

This thought leadership paper describes these challenges and presents four matching approaches to overcoming them, both for COVID-19 and for the practice of medicine. Practical recommendations include: ensuring hospitals generate timely and accurate data, obtaining a comprehensive and longitudinal view of the patient, transforming data into relevant diagnostic insights, and ensuring hospital leaders support an enterprise-wide approach to the relevance and the systemic execution of diagnoses. In the case of COVID-19, the learning and implementation of these four approaches have been leveraged by the overwhelming pressure on delivering a timely and accurate diagnosis. The solutions described here are generalizable beyond COVID-19 and can have a positive impact across all specialties.

## Challenges

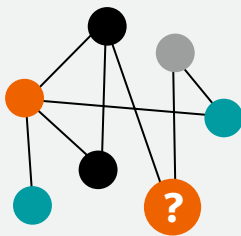
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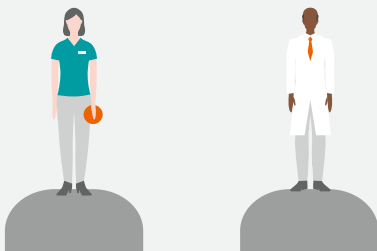
1. Low-quality, inaccurate, or incomplete data/test results



2. Diagnostic data that misses the “big picture”



3. Diagnostic information that is too complex or specialized to be actionable



4. Siloed and departmentalized diagnoses

## The challenges

COVID-19 presents numerous diagnostic challenges: the need for rapid turnaround time for results, the surge in demand for test kits, the diagnosis of asymptomatic patients, and the limitations of the tests themselves (i.e., false negatives during the “window” period just after infection). In addition to these known challenges, there are unknowns – does exposure confer immunity, what is a patient’s long-term prognosis after COVID-19, and what is the “best” diagnostic approach?

Diagnostic challenges are not unique to COVID-19. By some estimates, in the medical practice patients may be medically misdiagnosed 10%-15% of the time<sup>1</sup>, making it likely that most people will experience at least one diagnostic gap in their lifetime. Equally important, the diagnosis might not be specific enough to identify diagnostic subcategories to guide a tailored treatment for the patient.

The disruptions to healthcare in the wake of COVID-19 have only served to highlight the importance of accurate diagnosis for every medical condition and for every patient.

*“Half of the medicines we use don’t work. The reason is we are actually treating the wrong disease.”<sup>2</sup>*

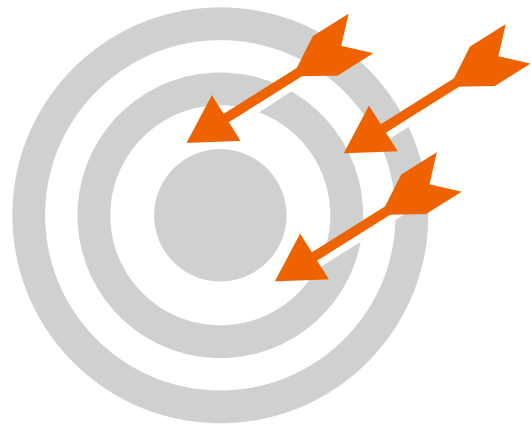
Paul Rothman, MD, PhD, Dean of the Medical Faculty & CEO, Johns Hopkins Medicine, U.S.

**1 Low-quality, inaccurate, or incomplete data/test results**

Test-related factors like low sensitivity or specificity or data subjectivity limit diagnostic accuracy. In the case of COVID-19, the window period with polymerase chain reaction (PCR) and low antibody specificity might lead to underestimates or overestimates of infection/exposure due to false positives or false negatives. And limited access to test collection supplies, coupled with limited availability of both reagents and appropriate analyzers, prevents some hospitals, clinics, or even regions from assessing the true extent of the COVID-19 pandemic.

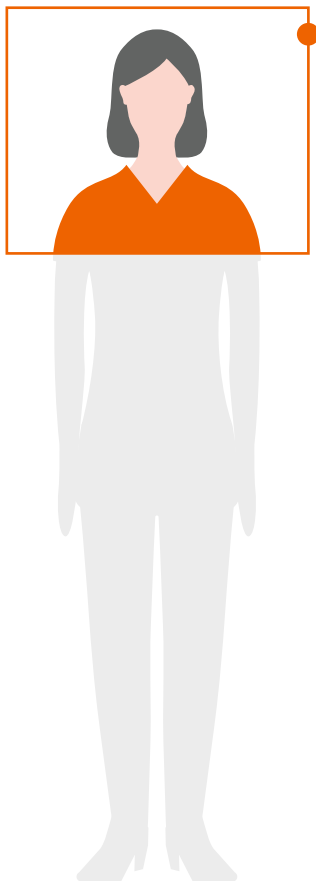
Reimbursement issues and lack of contact tracing infrastructure can keep public health officials from learning who needs to be tested for COVID-19 in order to limit further community transmission.

The challenges of data quality and quantity are not unique to COVID-19; they are common across the practice of medicine.



*“Acquired data often insufficiently represents the individual patient in front of the physician.”<sup>3</sup>*

Prof. John D. Halamka, MD, MS, Professor of Medicine, Harvard Medical School



## **2** Diagnostic data that misses the “big picture”

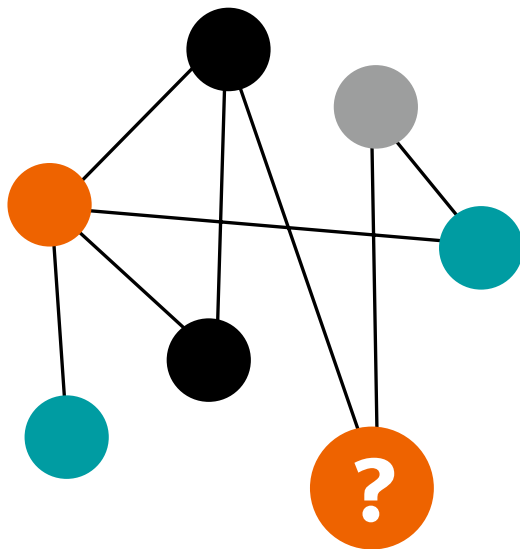
Lack of patient longitudinal data limits diagnostic and tracing efforts, making it more difficult to prevent outbreaks in a patient’s community or workplace. Too often, diagnostic data is only a snapshot, a picture of a specific factor or system at one point in time. When the COVID-19 pandemic erupted, a patient’s medical history and travel history were not always available when the patient arrived at the care facility, making it more challenging to accurately diagnose COVID-19.

A specific sub challenge is the lack of access to comprehensive information at the point of decision. The data infrastructure in many healthcare organizations makes it difficult to bridge the information gap between departments and organizations. In many countries, the need for an integrated digital infrastructure that makes all relevant information available to the caregiver and the patient has become painfully visible during the COVID-19 pandemic. Limited information on patients’ behavioral history and family life can hide risks, potentially limiting patients’ compliance to specific treatments or to preventive measures like self-isolation.

To deliver the best care to the patient and their community, a more thorough longitudinal understanding of that patient as a person and as a member of their community should be available to healthcare providers.

*“Data doesn’t do you any good until you can turn it into information, and that is really our challenge.”<sup>5</sup>*

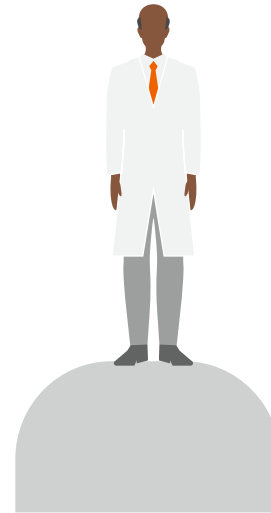
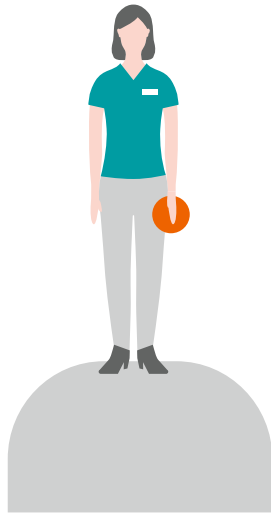
Stanford Medicine (2017): Health Trends Report: Harnessing the Power of Data in Health



**3 Diagnostic information that is too complex or specialized to be actionable**

COVID-19 challenges include assessing a high volume of data from many patients. Complex tasks, like assessing chest imaging with suspicious readings, as well as support in interpreting conflicting results (on molecular and antibody tests, for example), must be completed in a timely manner in order to appropriately diagnose and care for the individual patient.

In medicine in general, the total volume of data is growing at a rate of 48% per year, presenting a huge challenge to healthcare providers, who may be acting on outdated information. Many hospitals and health systems lack the scalability, performance, and analytic capability to support clinical decision-making and to make timely and targeted care interventions.<sup>4</sup>



#### **4 Siloed and departmentalized diagnoses**

Diagnosis is too often seen as a siloed department-level process, not a systemic hospital-wide one centered on the patient. The issues with organizational awareness on the relevance of diagnosis, as well as limitations of digital infrastructure mentioned in our previous *Insights* publication on public health, play a part here, limiting the speed and specificity of many diagnoses.

Only 19% of the organizations surveyed – 1 in 5 – are fully equipped to make enterprise-wide data-driven decisions, based on a recent survey.<sup>6</sup>

#### **COVID-19 and the need for precision diagnosis**

At the outset of the COVID-19 pandemic, many questions concerning when, how, and who to test needed to be addressed nimbly, across organizations, cities, and even countries. Clinicians had no choice but to quickly learn to improve overall accuracy and efficiency in the diagnostic process.

Many tests for PCR and antibodies were developed, but not all were properly validated. Even now, there is no test that is 100% accurate, so we need to use the most accurate tests available to limit inaccurate PCR and antibody results.

There are still a lot of unknowns – for example we don't know if antibodies confer immunity and if so, for how long; and we don't know how specific immunity may be to mutated virus strains. Continuously improving the quality of data that we generate on COVID-19 is vital to enhancing our understanding of the disease and how to prevent and treat it.

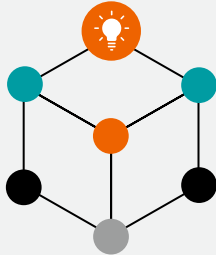
The relevance of these factors on non-transmissible conditions is built upon the same pillars for improving diagnostic accuracy in medicine. For example, in oncology: "The first step in identifying the right cancer treatment and achieving the best possible outcome is making the most accurate and precise diagnosis,"<sup>7</sup> said Marshall Hicks, MD, professor and head of the Division of Diagnostic Imaging at MD Anderson.



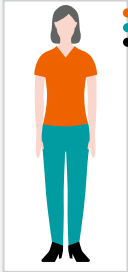
# Solutions to improve diagnostic accuracy



1. Improve data quality



3. Generate actionable insights from large and complex data sets



2. Provide comprehensive longitudinal data at the point of decision



4. Build executive support and enterprise culture for precision diagnosis



## Solution 1: Improve data quality

The two main types of testing for COVID-19 are PCR testing for active infection and antibody (or serologic) testing to determine recent or prior infection with SARS-CoV-2. Together, these two tests can help health agencies get a clear picture of the state of the pandemic. For accurate diagnosis, these tests must be validated and must offer a sensitivity and specificity close to 100%. Lower specificity in areas with low exposure to the virus might lead to over-estimates of community exposure due to false positive results. Accurate and widespread testing helps assess community status and identify infection “hot spots.”

How much COVID-19 testing is needed? The recommendation from health organizations and thought leaders is to conduct widespread testing in order to identify and contain outbreaks.<sup>8</sup>

In many countries, an initial gap or learning curve was identified between the ideal number of tests for mitigation and suppression and the actual testing being done. Further strengthening of testing programs was necessary to close these gaps.

Beyond improved tests, data should transition, when possible, from non-structured or qualitative into structured or quantifiable. Quantifiable data allows for more precise diagnosis and subclassification. For example, generation of quantitative or semiquantitative results for COVID-19 antibody titers will be important to characterize the immunity, if any, conferred by prior exposure to SARS-CoV-2.



### PCR testing

Molecular testing detects viral RNA, indicating an active disease state



### Serologic (antibody) testing

Detects patient’s prior exposure to SARS-CoV-2, the virus that causes COVID-19

## **Solution 2: Provide comprehensive longitudinal data at the point of decision**

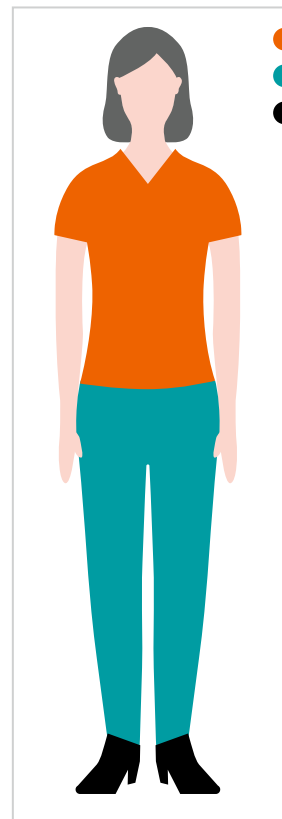
### **a) Getting the true picture of the individual patient**

COVID-19 taught us that the diagnostic process does not need to occur strictly in a practice or hospital. It can begin at home, for example, using a smartphone or a PC, bolstered by digital tools such as patient portals, digital tracers, screening algorithms, point of care technology, remote access, and telemedicine.

This broader approach to diagnosis, and to understanding the “whole patient” incorporates lifestyle data, which can be crucial to mitigating the spread of infectious disease. For patients with suspected COVID-19, the picture of the “whole patient” includes previous tests, travel history, and tracing data. Smart watches can provide additional data, including heart rate and temperature changes, that can be important in early screening the potential presence and severity of infection.

In other conditions, similar insights can be gained by incorporating sensors that track exercise, diet, sleep patterns, heart rhythms, and more. This data can be analyzed and visualized to present a more complete longitudinal picture of the patient to allow more tailored and proactive interventions.

Comprehensive longitudinal data is especially important in a rapidly evolving situation like COVID-19, where our understanding of the virus and the disease it causes are developing quickly. Access to comprehensive data can help identify important trends that emerge as our understanding increases.































**b) Making comprehensive data available at the point of decision**

The relevant longitudinal patient data discussed above should be readily available when making urgent decisions in any healthcare setting, including telehealth or home care settings.

Digital enablers and infrastructure are needed to guarantee secure access across settings (e.g., ambulatory, hospital admissions, home care, cell phones). Healthcare provider organizations must invest in digital enablers for secure information transfer, and more importantly, must develop an enterprise-wide strategy for secure data access and sharing.

**Seeing the whole patient: Gathering data and insight across multiple traditional and remote care settings**

Task	Collects data on patients remotely (e.g., at home)	Transmit data to health care provider in a different location	Evaluate data and notify health care providers as needed	Evaluate data and notify health care providers as needed
Radiologist analyzing imaging (e.g., CT scans, x-rays)				
Urgent care physician conducting a virtual visit with a patient				
Asthma patient using a mobile app to track symptoms for her personal review				
Patient communicating with primary care physician via a secure patient portal				
Hypertensive patient using a remote blood pressure cuff that automatically transmits information to physician				
Diabetic patient using a mobile app to track blood sugar readings that are transmitted to endocrinologist				
Parkinson's disease patient wearing a sensor that measures bradykinesia and transmits information to neurologist				

*Modified based on Harvard Business Review, July 2020: How to Make Remote Monitoring Tech Part of Everyday Health Care, Sanders MD et al.*

*“The more comprehensive and structured the available information is, the better the basis for decision-making and the better the decisions made on this basis are, as a rule.”<sup>9</sup>*

Schneider, UK: Einrichtungsübergreifende elektronische Patientenakten: Zwischen Datenschutz und Gesundheitsschutz

### **Solution 3: Generate actionable insights from large and complex data sets**

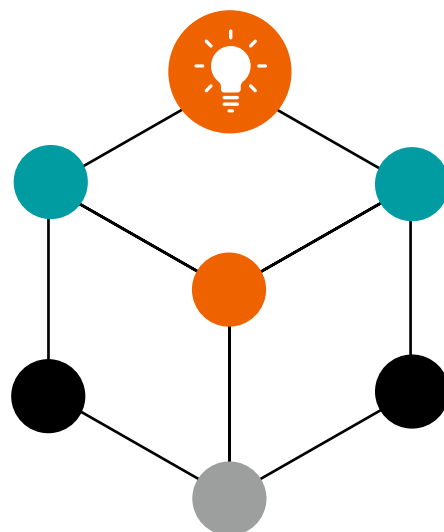
High-quality data is important, but what we do with it is even more so. Physicians must be able to translate data into actionable insights to deliver personalized medicine.

For example, consider chest computed tomography (CT) scans or X-rays. AI-powered decision support systems can help radiologists identify suspicious areas for evaluation or even suggest diagnoses that could be considered, based on analysis of many similar cases. This is especially important for patients with rare conditions, atypical presentations, or confounding physiological or pathological factors.

COVID-19 transcends the definition of a “respiratory disease.” Its symptoms can mimic other conditions (i.e.: gastrointestinal disease, flu, conjunctivitis), making it exceedingly challenging to diagnose and treat. Clinical decision support algorithms can help healthcare providers arrive at the right diagnosis in the face of such complexity and may help avoid ruling out COVID-19 in atypical presentations.

As mentioned earlier, it’s vitally important to incorporate other aspects of the patient’s life and health history. We’ve learned from COVID-19 how the economic and behavioral consequences of the pandemic triggered an unprecedented impact in mood problems and stress, affecting many activities of daily life. A proper evaluation of mental health is key to accurate and actionable diagnosis and effective

treatment. Incorporating factors that may influence patient compliance or, in the case of COVID-19, disease-spreading behavior, is a vital part of precision medicine. Digital tools can help evaluate patients’ likelihood to adhere to treatment and can also be used to promote improved adherence.



### ***Did you know?***

*AI-powered tools can automate quantitative measurements of imaging data. There are tools that can even perform risk stratification to guide treatment.*

#### **Real-world ways to make complex data actionable**

**Digital enablers:** AI-based tools can support complex integration of multiple data sources and comparison of individual patient data with aggregated data sets to streamline and improve clinical decision-making. Today, there are tools available that aid in a specific field, as in aiding in interpretation of imaging data, and other tools that incorporate multiple data sources (imaging, lab, EHR, etc.) to suggest a treatment pathway.

This can apply to population health concerns as well. Streamlined access and integration of multiple data sources, coupled with automation, can accelerate contact tracing in the wake of COVID-19 diagnoses, which is key to suppressing potential outbreaks.

“Despite technical and regulatory challenges, the apparent clinical and economic utilities of CDSS (clinical decision support systems) must lead to greater engagement. These tools play the key role in realizing the vision of a more ‘personalized medicine’, one characterized by individualized precision diagnosis...”<sup>10</sup>, Arnaud Belard, Chief of Operations – USU at The Henry M. Jackson Foundation, MD, U.S.

#### **Proactive identification of higher-risk subpopulations:**

An infectious disease suppression strategy includes aggressive, consistent testing of high-risk persons so communities can contain emerging COVID-19 case clusters faster.

Integrating data sources from multiple regions and from as many cases as possible allows national health organizations to form effective strategies for identification of and outreach to high-risk populations.

“I’m much more interested in figuring out who is likely to be infected and bringing the tests to them rather than testing an entire state,”<sup>11</sup> explains Jennifer Nuzzo, an epidemiologist at Johns Hopkins. Robust testing of high-risk groups could help pinpoint diagnoses, as well as facilitate prevention and early detection.

*“The diagnostic process is a complex, patient-centered, collaborative activity that involves information gathering and clinical reasoning with the goal of determining a patient’s health problem.”<sup>12</sup>*

#### **Solution 4: Build executive support and enterprise culture for precision diagnosis**

Precision diagnosis is a systemic process, requiring buy-in at every level of the organization. Top management involvement and endorsement are essential to garnering support for and adoption of a precision diagnosis culture and the necessary integration of care teams and infrastructure to enable that culture to thrive. “This process occurs over time, within the context of a larger healthcare work system that influences the diagnostic process.”<sup>12</sup>

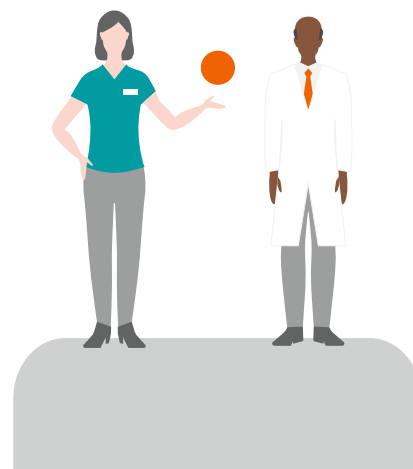
During the COVID-19 pandemic, engagement and support at the executive and enterprise level accelerated the realization of the relevance of the diagnosis. In parallel, the CDC and other agencies provided templates for addressing the overall diagnostic process, including subclassification of patients based on clinical severity and guidance for appropriate management. These were important first steps toward adopting an integrated, enterprise-wide approach to precision diagnosis.

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#### **Diagnosis: Its systemic components**



For COVID-19, the flow of real-time diagnostic information across departments and healthcare professionals allowed the needed integration of care teams in the diagnostic process in different clinical settings (home care, nursing care, ER, surgery, etc.).



# Conclusions

**COVID-19 has put a spotlight on specific challenges in diagnosis and the rewards of improving diagnostic accuracy and speed. The ability to make a data-driven diagnosis is one of the most fundamental skills in the healthcare armory. Low data quality, non-comprehensive data, overly complex or non-actionable data sets, and a lack of organizational infrastructure can hamper physicians' ability to consistently make data-driven diagnoses. A fragmented view of a patient must give way to a more comprehensive, longitudinal perspective for precise characterizations of diseases. And a fragmented view of diagnostic processes must give way to an integrated, enterprise-wide approach to precision diagnosis.**

We identified four action-oriented insights to be considered by executive leadership at hospitals and other healthcare institutions:

1. Ensure that hospitals generate accurate, high-quality data in terms of specificity, sensitivity, and quantification.
2. Consider processes and technology to capture comprehensive and longitudinal data. This includes continuous data at non-hospital locations (home, gym, at work, ambulatory, ER, ICU) and leveraging new wearables, like smart watches and other sensors, when appropriate. While complying with privacy and security, a more comprehensive, longitudinal approach to patient health data supports proactive, preventable, and early diagnosis decisions.

3. Give clinicians help in assessing complex data. AI-based clinical decision support systems can help physicians process the potentially overwhelming burden of complex data in order to understand underlying pathologic processes and treat patients accordingly.
4. Obtain C-level buy-in on the enterprise-wide relevance of precision in diagnosis. Leaders of healthcare enterprises should clearly demonstrate the value of a systemic approach to diagnosis to the heads of departments to foster an integrated approach. Encourage a patient-centric approach and cross-departmental collaboration to deliver the best results.

The way forward is clear and rewarding, but it is by no means easy. Some of these solutions are departures from "business as usual" and require executive support, as we experienced with COVID-19.

We are at a crossroads, where the digitalization of medicine is making integrated data-driven approaches to diagnosis and treatment a real possibility. Technology is also enabling decentralized care and precise remote monitoring, so that physicians will have greater insight than ever before into the mechanisms of disease and how they affect patients' lives.

Now is the time for healthcare leadership to adopt a precision diagnostic mindset, to embrace the integrated approach to diagnosis, and help their care teams develop robust insights for effective and proactive diagnosis and prevention.




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 **Suggested readings**

Lasalvia L., Merges R. (2020) Insights Series, issue 11: Moving toward precision in managing pandemics: 5 critical domains for success in public health. Available on [siemens-healthineers.com/insights/news/moving-toward-precision-in-managing-pandemics.html](https://siemens-healthineers.com/insights/news/moving-toward-precision-in-managing-pandemics.html)

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 **Information**

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 **Contact**

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# About the authors



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Vice President, Global Medical Officer  
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Dr. Luis Lasalvia's experience in clinical practice combined with his versatile career in pharmaceutical and medical device technologies has been inspiring and driving the delivery of concrete high value. He's led a variety of numerous scientific, business and partnership teams, served as an advisory board member, and developed large programs and new ventures, including more than 30 novel and large programs in the U.S. and multiple countries in Europe.

Dr. Lasalvia has been a keynote guest speaker, panelist, and moderator at about 500 events and conferences around the world, has authored more than 50 peer-reviewed papers and articles in prestigious publications, and has submitted multiple patents in Europe and the U.S.

He lives in New York and is a Medical Doctor from University of the Republic in Montevideo. He holds a Master's degree in International Business from Pompeu Fabra University in Barcelona; and Executive education at The Wharton School of Business in Philadelphia, New York University, New York City, and Harvard Business School in Boston.



**Reto Merges**  
Global Head Expanding Precision Medicine  
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With more than 10 years' leadership experience in healthcare marketing, Reto Merges has a strong track record in building effective teams for clinical and innovation marketing. In addition, he has four years of work experience in China, ramping up efforts for research collaborations in China and South Korea. He holds a degree in electrical engineering and information technology from the Karlsruhe Institute of Technology, Germany, and has studied at the Nanjing Normal University, China. His scientific background is in the field of medical imaging, where he has authored many publications and holds multiple patents.

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10. Belard A et al. Precision diagnosis: a view of the clinical decision support systems (CDSS) landscape through the lens of critical care. *J Clin Monit Comput.* (2017) Apr;31(2):261-271.
11. Coronavirus by the numbers (2020) NPR. As Coronavirus Surges, How Much Testing Does Your State Need To Subdue The Virus?
12. Improving Diagnosis in Health Care, National Academies of Sciences Engineering, and Medicine. (2015). Improving Diagnosis in Health Care. Washington, DC: The National Academies Press.

At Siemens Healthineers, our purpose is to enable healthcare providers to increase value by empowering them on their journey towards expanding precision medicine, transforming care delivery, and improving patient experience, all enabled by digitalizing healthcare. An estimated five million patients worldwide benefit every day from our innovative technologies and services in the areas of diagnostic and therapeutic imaging, laboratory diagnostics and molecular medicine as well as digital health and enterprise services.

We are a leading medical technology company with over 120 years of experience and 18,500 patents globally. With about 50,000 dedicated colleagues in over 70 countries, we will continue to innovate and shape the future of healthcare.

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