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Market Trends: Unprecedented Funding Boom for Digital Health Led with Software & Mental Health

Investors are directing more of their money to health care digital technology companies than they ever have before. In 2020, total fundraising in digital health was \$14.6 billion, the first time the sector ever surpassed the \$10 billion barrier. Only three quarters into 2021, total funding for the year already stands at \$21.3 billion. These are among the key findings of a new [report](#) from venture capital analyst firm Rock Health.

The Digital Health Sector

Rock Health’s analysis of digital health funding includes companies that build and sell technologies, including those

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DX Deals: Becton Dickinson Lands \$40.3 Million BARDA Contract to Develop 510(k)-Worthy COVID-19 Tests

Global medical tech company Becton Dickinson (BD) has been a leader in the effort to pioneer new diagnostic tests for COVID-19, having obtained FDA Emergency Use Authorization for COVID-19, flu A, and flu B combination tests that run on both the BD Max and BD Veritor Plus platforms. BD is now seeking to take things to another level by teaming with the Biomedical Advanced Research and Development Authority (BARDA) on a government contract designed to create novel combination COVID-19 assays that will garner full 510(k) clearance.

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paired with a service where the technology itself is the service. That includes companies like data warehouse platform builder Health Catalyst, online preventive health programs designer Omada Health, and Sotera Wireless, developer of the ViSi Mobile System. Rock Health excludes companies like Access MediQuip, Oscar, One Medical and other firms that are innovative but focus on selling labor-intensive services, rather than technology. The analysis also counts only deals of \$2 million or more.

The Quantitative Analysis

Rock Health describes 2021 as a “blockbuster year” for digital health funding, with the three highest-funded quarters ever. The \$8.2 billion posted in 2021 Q2 was higher than total funding for the entire year in 2019. However, funding dropped off just a tad in Q3, at \$6.7 billion. Still, Q3 funding surpassed the total \$6.4 billion of 2021 Q1, making it the second-highest quarter ever for digital health funding.



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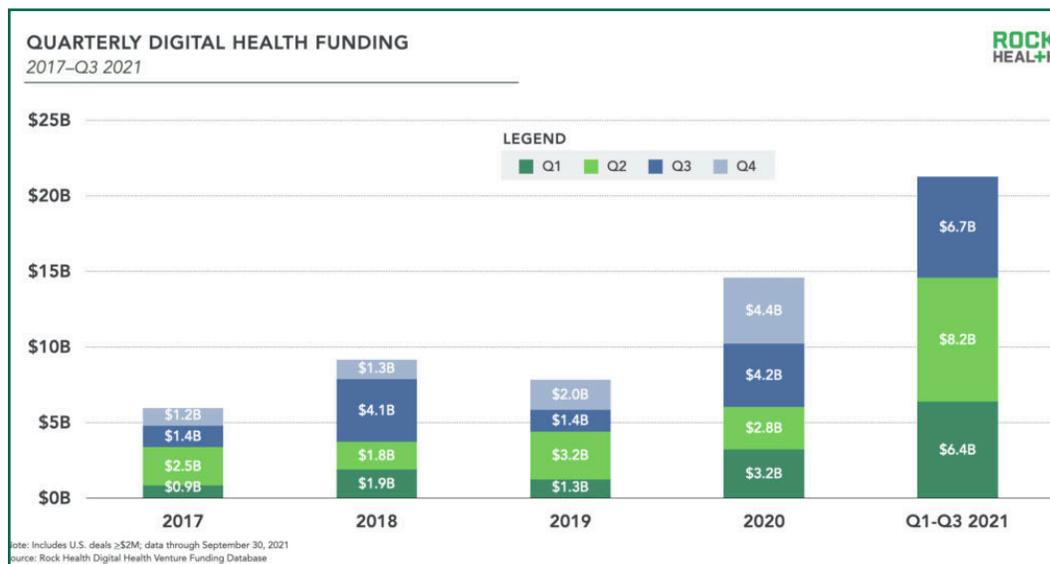
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Deal volume followed the same basic pattern, with 169 deals in Q3 2021, as compared to the record-breaking total of 223 in Q2. Deal size was more evenly spread out during Q3, with only 15 “mega deals,” as opposed to the 22 posted in Q1 and 25 in Q2. The mega deals accounted for \$3.1 billion, or less than half of all funding for 3Q; by contrast, mega deal totals contributed \$4.1 billion and \$4.5 billion to the totals for Q1 and Q2, respectively, well over 50 percent of total funding for each particular quarter.

The Narrative: Investment Patterns

Investment flows in digital health for the first three quarters of 2021, according to Rock Health, were consistent with patterns of previous years,

with companies using software to accelerate research and development, delivery of on-demand healthcare services and support disease treatment raising the most money

Mental health was the highest-funded clinical area, with \$3.1 billion raised. “As digital mental health companies compete in an increasingly crowded space,” the report notes, “we’re seeing more startups differentiate by focusing on complex mental and behavioral health support, including serious mental illness and substance use disorders.” Recent big deals cited in the report include:

- ▶ The \$64 million raised by Quit Genius in July;
- ▶ The \$16 million raised by Lucid Lane in August; and
- ▶ The \$33 million invested in NOCD in September.

The Narrative: Demographic & Social Patterns

The Rock Health analysis also looks at 2021 investment flows from a societal perspective, identifying three themes:

1. More Money Being Raised by Female CEOs

The report finds that companies led by female CEOs have been closing more private market digital health deals than ever before, with \$3.0 billion raised across 103 deals so far in 2021. Female CEO companies have accounted for 19 percent of all the year’s deals, the highest percentage Rock Health has ever seen since it began tracking digital health funding patterns. That finding is consistent with previous year’s reports showing that female CEO funding has been steadily ticking up each year since 2017, when those deals accounted for only 11 percent. On the downside, Rock Health says that female-led companies are raising less money, on average, relative to their male-led counterparts (\$29 million per deal vs. \$42 million per deal in 2021).

2. More Money Going to Women's Health

The second trend is the continuing growth of funding in what Rock Health describes as “women+health”, i.e., companies serving the health needs of women, including cisgender women identifying as transgender or nonbinary. Through August 2021, digital health startups serving women+health raised \$1.3 billion, nearly doubling the \$774 million in total funding for all of 2020. This has been a record year for women+health companies, with \$443 million raised in 2021 Q3, the second-highest funded quarter ever for the segment, surpassed only by the \$631 million raised in Q1.

3. More Money Going to Companies Supporting Health Equity

Companies designed to serve the socially disadvantaged and eliminate the health care disparities exposed by the pandemic and recent movements

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for social justice have also figured more prominently in 2021 digital health care funding, according to Rock Health. Examples cited by the report:

- ▶ Soda Health raised \$6 million to launch a social determinants of health benefits platform;
- ▶ MiSalud secured \$5 million for its health and wellness app for the Latinx community;
- ▶ Alkeme Health attracted \$3.5 million for its digital mental health platform tailored to the Black experience; and
- ▶ Cayaba Care raised \$3.2M to build out digital care offerings for underserved mothers.

Takeaway

Investors are sinking capital into digital health companies like they never have before, with software companies continuing to command the lion's share of the funding. Clinically, mental health remains the top draw. At the same time, demographic and social developments, including the emergence of female CEOs and stepped-up efforts to redress injustices and disparities in health care are exercising a growing influence on investment patterns.

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FDA WATCH

Agency Takes Steps to Promote Scientifically Sound Development of AI-Based Medical Devices

The FDA is stepping up its efforts to regulate the development of medical devices that use artificial intelligence and machine learning (AI/ML) technologies. Here's a briefing on a pair of significant initiatives that the agency unveiled in the past six weeks.

The AI/ML Action Plan

On Sept. 22, the agency published an [Action Plan](#) setting forth five actions it intends to take to advance sound, safe and effective development of AI/ML-based medical devices:

1. Issue draft guidance for modification of algorithms in AI/ML software as a medical device (SaMD) over time;

2. Promote Good Machine Learning Practice (GMLP), i.e., AI/ML best practices for data management, feature extraction, training, interpretability and evaluation that are akin to good software engineering practices;
3. Hold a public workshop on how device labeling supports transparency to users and enhances trust in AI/ML-based devices;
4. Support regulatory science efforts to develop methodology for evaluating and improving machine learning algorithms, including via identification and elimination of bias; and
5. Support the piloting of real-world performance (RWP) monitoring for SaMD.

The AI/ML Best Practices Guidelines

On Oct. 27, the FDA and its counterpart agencies in Canada and the United Kingdom issued joint [guidelines](#) for companies developing The FDA, Health Canada and U.K. Medicines and Healthcare Products Regulatory Agency outline 10 “guiding principles” for companies that develop AI/ML-based medical devices:

1. Leverage multi-disciplinary expertise throughout the total product life cycle;
2. Implement Good Software Engineering and Security Practices;
3. Ensure that relevant characteristics of the intended patient population (e.g., regarding age, gender, sex, race, and ethnicity), use and measurement inputs are sufficiently represented in a sample of adequate size in the clinical study and training and test datasets, so that results can be reasonably generalized to the population of interest;
4. Ensure that training and test datasets are appropriately independent of one another;
5. Select referenced datasets upon best available methods;
6. Tailor model design to the available data and ensure that it reflects the device’s intended use;
7. Account for human factors in evaluating performance of models that include a “human in the loop”;
8. Ensure that testing of device performance is carried out in clinically relevant conditions;
9. Provide device users clear, essential information; and
10. Monitor models that are deployed in real world condition with a focus on maintaining or improving safety and performance.

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■ **FDA Watch: Agency Takes Steps to Promote Scientifically Sound Development of AI-Based Medical Devices,**
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As the AI/ML medical device field evolves, so too must [Good Machine Learning Practice] best practice and consensus standards, the new guidance notes.



Here are some of the key new FDA EUAs and clearances announced in October 2021:

New FDA Emergency Use Authorizations (EUAs) & Approvals

Manufacturer(s)	Product
InBios International	EUA for SCoV-2 Detect Neutralizing Ab ELISA immunoassay
Celltrion	EUA for over-the-counter, at-home SARS-CoV-2 antigen test
Biological Dynamics	Breakthrough device designation for Exo-PDAC liquid biopsy assay
Cognetivity Neurosciences Ltd	Clearance for CognICA, 5-minute, computerized cognitive assessment for detecting dementia done on an iPad
Thermo Fisher Scientific	EUA for using saliva samples collected with Spectrum Solutions SpectrumDNA SDNA-1000 collection device for COVID-19 tests run on Amplitude Solution
Lighthouse Lab Services	EUA for RT-PCR-based CovidNow SARS-CoV-2 Assay
Xtrava Health	EUA for SPERA COVID-19 Ag Test lateral flow immunoassay
Agilent Technologies	Clearance for Ki-67 IHC MIB-1 pharmDx (Dako Omnis) assay to identify early breast cancer patients who can be treated with Eli Lilly's abemaciclib (Verzenio) in combination with endocrine therapy
Cleveland Clinic	EUA for SelfCheck Cobas SARS-CoV-2 Assay
Quanterix	Breakthrough device designation for Alzheimer's blood test run on the Quanterix HD-X immunoassay system
Nonagen Bioscience	Breakthrough device designation for Oncuria non-invasive bladder cancer test
Quest Diagnostics	EUA for at-home Collection Kit for COVID-19
PerkinElmer	EUA for PKamp Respiratory SARS-CoV-2 RT-PCR Panel 1 assay to detect SARS-CoV-2 and the flu
Euroimmun	EUA for Anti-SARS-CoV-2 S1 Curve ELISA test
Acon Laboratories	EUA for Flowflex COVID-19 Home Test over-the-counter antigen test
OpGen	510(k) clearance for Acuitas AMR Gene Panel
LabCorp	EUA for combined home collection kit for molecular testing for COVID-19 and influenza A/B.

New CE Marks & Global Certifications

Notable European CE certifications announced during the period:

NEW CE MARKINGS IN EUROPE

Manufacturer(s)	Product(s)
Intelligent Fingerprinting	VSS-GP COVID-19 Saliva Test
GenomSys	GenomSys Variant Analyzer
BioMérieux + Baxter	Nephroclear CCL14 Test for detecting acute kidney injury
Agilent Technologies	PD-L1 IHC 28-8 pharmDx as companion diagnostic test to guide treatment of adult patients with HER2-negative advanced or metastatic gastric, gastroesophageal junction or esophageal cancers
Sorrento Therapeutics	Covistix SARS-CoV-2 rapid antigen test
Qiagen	QiaReach QuantiFeron-TB test for tuberculosis infection
Biopix-T	COV19 qcLAMP kit + point-of-care Pebble qcLAMP Platform it runs on
Cepheid	Xpert Xpress CoV-2/Flu/RSV plus rapid molecular diagnostic test for SARS-CoV-2, influenza A and B, and respiratory syncytial virus
Genematrix	NeoPlex HPV29 Detection kit for human papillomavirus
Takara Bio Europe	Takara SARS-CoV-2 Direct PCR detection kit
Genedrive	Next generation of Genedrive System gene amplification platform

Other international clearances announced during the period:

Manufacturer(s)	Country(ies)	Product(s)
LumiraDx	India	SARS-CoV-2 Antigen test



M&A Report: PerkinElmer Acquires BioLegend While FTC Warns Against Non-Approved Mergers

M&A activity in the general healthcare sector has yet to rebound from COVID-19. However, while overall deal numbers remain below pre-pandemic historical averages, deal size has increased. According to financial consultant Kaufman Hall, there were only 14 health system M&A transactions in the second quarter of 2021; but revenue from those deals was \$8.5 billion, the second highest total in five years.

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■ M&A Report: PerkinElmer Acquires BioLegend While FTC Warns Against Non-Approved Mergers, from page 7

PerkinElmer Closes \$5.25 Billion BioLegend Acquisition

M&A in the diagnostics sector is following the same basic pattern. Perhaps the biggest story in the past two months was the announcement that one of the year's biggest deals to date, PerkinElmer's \$5.25 billion acquisition of antibodies and reagents provider BioLegend, has closed. PerkinElmer has been aggressive on the M&A front, but this is the biggest acquisition in company history. With more than 700 employees and \$380 million in expected revenues, addition of San Diego-based BioLegend establishes PerkinElmer's presence in new segments of the life sciences market. The plan is to make BioLegend's San Diego campus PerkinElmer's global center of excellence for research reagent content development.

The acquisition makes PerkinElmer a “best in class preclinical, life sciences franchise that is uniquely positioned to empower our external powers to deliver truly legendary discoveries over the coming years,” according to company President and CEO Prahlad Singh in a statement. The combination creates a “true powerhouse that will have the skill to be able to accelerate scientific advancement and new product innovation across the company and around the world.”

FTC Sounds the Warning on Unapproved Mergers

Meanwhile, regulatory pressures cast a growing shadow on future deal making. Rocked by a “tidal wave” of premerger filings, the U.S. Federal Trade Commission (FTC) has been sending out letters warning that companies that merge without agency full agency review do so “at their own risk.” The FTC reportedly received 343 premerger filings in July, as compared to 112 in July 2020. The danger is that once the FTC does review the merger and determines that it's anticompetitive, the merging companies will have to unwind the deal. There have already been over 2000 filings for the year (through early August), more than twice the 815 total filed in all of 2020.

The FTC announcement comes weeks after President Biden's executive order instructing the FTC and other agencies to exercise additional scrutiny to limit anticompetitive M&A deals, including transactions involving hospitals and health systems.

Regulatory pushback is also coming from the other side of the Atlantic. In April 2021, the European Commission (EC) Directorate-General of Competition announced that it planned to review Illumina's proposed \$8.5 billion acquisition of former spinoff Grail. Rather than await the results of the EC investigation, Illumina closed the deal hoping to get regulatory approval later. In addition to the prospects of having to unwind the deal, Illumina now faces the risk of EC sanctions.



Here's a summary of the key new M&A diagnostic deals announced or closed in October 2021:

MERGERS, ACQUISITIONS & ASSET SALES

Acquiring Company	Target(s)	Deal Summary
23andMe	Lemonaid Health	<ul style="list-style-type: none"> • Price: \$100 million cash + \$300 million common stock • Status: Expected to close by end of 2021 • Acquisition of company offering online access to telemedicine and pharmacy services
Hologic	Bolder Surgical	<ul style="list-style-type: none"> • Price: \$160 million • Status: Expected to close by end of 2021 • Hologic advances strategy to build out its surgical franchise by acquiring provider of advanced energy vessel sealing surgical devices
Biotage	ATDBio	<ul style="list-style-type: none"> • Price: \$62 million in cash and stock • Status: Closed • Acquisition of UK-based oligonucleotide producer enables Swedish firm to expand into DNA and RNA oligonucleotide synthesis and purification
Castle Biosciences	Cernostics	<ul style="list-style-type: none"> • Price: \$30 million upfront (either all in cash or \$20 million in cash and \$10 million in Castle common stock) + up to \$50 million more in cash and/or common stock based on Cernostics' achievement of milestones in 2022 • Status: Expected to close by end of 2021 • Acquisition of company specializing in spatial biology and artificial intelligence-driven image analysis of tissue biopsies
Mesa Laboratories	Agena Bioscience	<ul style="list-style-type: none"> • Price: \$300 million cash • Status: Closed • Acquisition of mass spectrometry-based genetic analysis firm expected to add between \$63 million and \$67 million to Mesa's revenues during first year, excluding COVID-19 revenues
Everly Health	Natalist	<ul style="list-style-type: none"> • Price: All-cash transaction at undisclosed price • Status: Closed • Acquisition of women's health firm enables digital firm Everly to bolster its line of at-home collection lab tests for menopause, fertility hormones, sexual health and other women's health products
BICO Group	QInstruments	<ul style="list-style-type: none"> • Price: \$71.1 million, subject to adjustment for net cash/debt and deviation from normalized working capital • Status: Closed • Acquisition of producer of highly modular and customizable equipment for precision temperature control and molecular sample mixing bolsters BICO's diagnostics and omics automation offerings
Bionano Genomics	BioDiscovery	<ul style="list-style-type: none"> • Price: Up to \$100 million in cash and stock • Status: Expected to close by end of October • Portion of equity subject to vesting based on continued service of certain employees; portion of cash consideration contingent on full integration of OGM data into BioDiscovery's software platform • Bionano bolsters presence in digital cytogenetics and genome analysis markets by adding BioDiscovery's Nx Clinical software for analysis of genomic variants from microarray and sequencing data

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■ M&A Report: PerkinElmer Acquires BioLegend While FTC Warns Against Non-Approved Mergers, from page 9

Acquiring Company	Target(s)	Deal Summary
EKF Diagnostics	Advanced Diagnostics Laboratory (ADL Health)	<ul style="list-style-type: none"> • Price: \$10 million in shares + performance-based payments of up to \$60 million over next 3 years • Status: Expected to close in October • Acquisition of CLIA-certified testing lab focused on PCR for clinical, forensic, and microbiological tests, as well as COVID-19 testing
Fujifilm Medical Systems	Fujifilm Healthcare Americas	<ul style="list-style-type: none"> • Status: Closed • Merger with new entity to operate under the name Fujifilm Healthcare Americas

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Personalized Medicine: 23andMe Moves into Telehealth via \$400 Million Lemonaid Acquisition

It's been a busy year for 23andMe. Consumer DNA testing giant 23andMe. Less than five months after going public, the consumer genetic testing giant has made a major move to establish its position as a leader in DTC primary care by acquiring telehealth drug-delivery provider Lemonaid Health Inc. for \$400 million. Here's a look at the deal and its potential ramifications for the personalized DTC healthcare market.

The 23andMe Vision

Although it began as almost a novelty business offering saliva-based DNA tests that curious consumers can use to acquire information about their ancestry, 23andMe has harbored wider ambitions since launching in 2006. For current CEO and company founder Anne Wojcicki, the larger goal was nothing less than leveraging personalized genetic information to transform the way patients receive health care. "Genetics still has not been adopted into primary care," noted Wojcicki in an interview.

In 2015, 23andMe dipped its toes into the geneticization-of-primary-care waters by establishing a therapeutics unit charged with using the company's massive trove of genetic data to develop new drugs. Supporting the unit was a major reason for the company's decision to go public in June, according to Wojcicki.

23andMe Opens a Lemonaid Stand

On Oct. 22, 23andMe announced that it has reached an agreement to acquire Lemonaid Health Inc. for \$400 million, including \$100 million

in cash and \$300 million in common shares. The deal, which is expected to close by the end of the year, brings 23andMe a giant step closer to its vision of integrating itself into the primary care experience, from wellness through diagnosis to treatment and prescription.

Lemonaid operates a nationwide, on-demand telehealth platform offering remote access to medical care and pharmacy services, including online consultations and delivery of prescription medicines. The platform asks users to complete an online assessment providing details of their health history. A team of doctors and nurse practitioners then review the information, sometimes asking users questions, and then offering free delivery of prescription medicines.

The service operates on a sliding scale of payments, from \$25 for a telehealth visit, between \$10 and \$65 for lab tests and \$95 per month for ongoing care for chronic diseases like anxiety and depression. It covers conditions like urinary tract infections (UTIs), birth control, acne, hair loss, hypothyroidism, erectile dysfunction, sexually-transmitted diseases and insomnia, amongst others.

The Business Integration Plan

“We believe that by combining Lemonaid Health’s telemedicine platform ... with our consumer business, we are taking an important step in transforming the traditional primary care experience and making personalized healthcare a reality,” Wojcicki said. The immediate plan calls for training Lemonaid’s doctors how to harvest the potential of 23andMe’s pharmacogenetics reports for determining which drugs are likely to work best for a particular individual when prescribing drugs for Lemonaid customers. While there is no “defined product roadmap,” Wojcicki said the eventual goal is to create a mode of care that best makes use of genomic information.

Lemonaid chief executive officer and co-founder Paul Johnson will become general manager of 23andMe’s consumer business and run continue to run the division, according to the company statement. Ian Van Every, Lemonaid’s U.K. managing director, will remain in a similar role with 23andMe.

Takeaway

When the history of personalized, genetics-based DTC medicine is written many years from now, the wedding of 23andMe’s genetics data and consumer expertise with Lemonaid’s telehealth platform may prove to have been a pivotal moment. “By starting with genetics as the foundation, we will give patients and healthcare providers better information about health risks and treatments, opening up the door to prevent as well as better manage disease,” noted Wojcicki in a statement.

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■ **DX Deals:** Becton Dickinson Lands \$40.3 Million BARDA Contract to Develop 510(k)-Worthy COVID-19 Tests, from page 1

The BD-BARDA Collaboration

BARDA, a division of the US Health and Human Services’ Office of the Assistant Secretary for Preparedness and Response, and BD have formed public-private partnership to support development of combination diagnostic tests to detect COVID-19 and other targets at core labs, hospitals and the point of care. BARDA will provide \$24.7 million in initial funding, with options to extend up to \$40.3 million.

The 5 Target Tests

According to BD, the objective is to develop and gain 510(k) clearance for five different combination tests to create a panel for use at all levels of the healthcare system. The first test, the BD Veritor Plus System Respiratory Panel, will be a rapid point-of-care antigen test run on the BD Veritor system capable of detecting and distinguishing SARS-CoV-2, influenza A and influenza B.

The Franklin Lakes, New Jersey-based company will also develop four molecular assays, two for the BD Max and two for the BD Cor system. The BD Max assays are intended for use in hospitals and moderate throughput labs, including the:

- ▶ BD Max System Respiratory Panel to detect and distinguish between SARS-CoV-2, influenza A and B, and respiratory syncytial; and
- ▶ BD Max System Respiratory Panel plus Pan-Coronavirus to detect and distinguish between SARS-CoV-1, Middle East Respiratory Syndrome, seasonal coronaviruses and novel or emerging coronaviruses.

The firm will also develop two BD Cor system tests, the BD Cor System Respiratory Panel and BD Cor System Respiratory Panel plus Pan-Coronavirus, that reference labs and high-throughput diagnostics settings can use to detect and distinguish the same targets as the Max system panels.



Here’s a summary of other key strategic diagnostic deals announced in October 2021:

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS

Partner 1	Partner(s) 2+	Deal Summary
Roche	PathAI	<ul style="list-style-type: none"> • Objective: Develop and distribute AI-based digital pathology applications • Dynamic: Jointly create embedded image analysis workflow for pathologists enabling PathAI’s image analysis algorithms to be accessed within Roche’s Navify Digital Pathology cloud software

Partner 1	Partner(s) 2+	Deal Summary
Roche	Prenosis	<ul style="list-style-type: none"> • Objective: Improve sepsis detection • Dynamic: Expand current partnership enabling Prenosis to expand its NOSIS dataset • Partners also to seek FDA clearance for Prenosis Sepsis Immunoscore and Roche Elecsys IL-6 assay
Vibrent Health	Virginia Commonwealth University	<ul style="list-style-type: none"> • Objective: Launch new research platform to study genetic and environmental influences underlying individual differences in twins • Dynamic: Operating in collaboration with VCU Wright Center, Global Twin Research Platform consolidates data from otherwise disconnected twin registries, providing access to larger combined datasets
Inivata	Princess Margaret Cancer Centre	<ul style="list-style-type: none"> • Objective: Use Inivata's InVisionFirst-Lung and RaDaR liquid biopsy assays in two clinical lung cancer studies • Dynamic: Study 1 to compare how long it takes patients to begin non-small cell lung carcinoma treatment after diagnosis via liquid biopsy vs. conventional molecular testing after imaging and biopsy • Study 2 to use Inivata RaDaR assay to identify curative therapy candidates after lung cancer resection via signs of minimal residual disease
Imec	Johns Hopkins University	<ul style="list-style-type: none"> • Objective: Commercialize COVID-19 breathalyzer • Dynamic: Licensing agreement enabling Imec spinoff MiDiagnostics to start commercialization process
Caris Life Sciences	Ono Pharmaceutical	<ul style="list-style-type: none"> • Objective: Develop immune-based cancer therapies • Dynamic: Use Caris' molecular profiling technologies for studies of investigational targeted and immune-based cancer therapies
C2i Genomics	NuProbe Global	<ul style="list-style-type: none"> • Objective: Expand C2i's AI-based cancer platform and NuProbe's chemistry products and sequencing networks in China and US • Dynamic: Develop chemistry and software products expanding traditional whole-genome library preparation to include additional signal enrichment for cancer hotspots, microsatellite instability and fusions

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■ DX Deals: Becton Dickinson Lands \$40.3 Million BARDA Contract to Develop 510(k)-Worthy COVID-19 Tests, *from page 13*

Partner 1	Partner(s) 2+	Deal Summary
Personalis	Mayo Clinic	<ul style="list-style-type: none"> Objective: Offer clinical-grade comprehensive cancer genomic sequencing to patients Dynamic: Research collaboration to make results from Personalis' whole-exome and transcriptome sequencing results available to participating patients and their providers to guide therapeutic decisions
GeneDx	Krystal Biotech	<ul style="list-style-type: none"> Objective: Provide free genetic testing for epidermolysis bullosa, a rare skin disorder that Krystal is developing a treatment for Dynamic: Offer no-cost testing for all forms of EB, with goal of helping dystrophic EB patients get a diagnosis sooner
Destina Genomics	Mecwins	<ul style="list-style-type: none"> Objective: Develop RNA biomarker tests for drug-induced toxicity, as well as therapeutic RNAs Dynamic: Cross-licensing agreement enabling companies to share their RNA quantification technology with aim of reducing the risk of error in late-stage clinical trials and speeding development and implementation of scalable molecular tests
Deepcell	University of Zurich's Levesque Lab	<ul style="list-style-type: none"> Objective: Conduct study of the tumor microenvironment in melanomas Dynamic: Researchers to use Deepcell's platform for isolating cells based on morphological features rather than labeling or predefined biomarkers to sort cells for downstream molecular analysis
Laboratory Corporation of America	GeneCentric Therapeutics	<ul style="list-style-type: none"> Objective: Develop and commercialize RNA-based signatures for diagnosing cancer Dynamic: GeneCentric to develop signatures in collaboration with Labcorp Drug Development, with tests produced by the project deployed to major academic and community cancer centers through Labcorp Diagnostics
Invitae	Outcomes4Me	<ul style="list-style-type: none"> Objective: Develop mobile apps to improve education and access to genetic testing for breast cancer patients and survivors Dynamic: Allow patients to make a genetic counseling appointment and order testing directly from Outcomes4Me's platform

Partner 1	Partner(s) 2+	Deal Summary
Speedx Pty Ltd.	Syngenis	<ul style="list-style-type: none"> Objective: Develop a new at-home rapid PCR test ensuring that Australia can become self-sufficient in producing PCR tests Dynamic: Speedx Pty Ltd. to invest Syngenis, a Perth-based startup that makes raw materials needed for PCR COVID-19 tests
DNAe	Imperial College London + University of Leicester	<ul style="list-style-type: none"> Objective: Develop liquid biopsy test to monitor treatment and detect early recurrence of breast cancer Dynamic: Leverage DNAe's next-generation sequencing technology to create test
Blueprint Genetics	BioMarin	<ul style="list-style-type: none"> Objective: Provide free genetic testing for people suspected of having inherited skeletal dysplasia Dynamic: Launch free testing program for physicians in Europe and Middle East
Genetron Health	Jiangsu Fosun Pharmaceutical Sales (subsidiary of Shanghai Fosun Pharmaceutical)	<ul style="list-style-type: none"> Objective: Commercialize Genetron Health's minimal residual disease assay Seq-MRD in China Dynamic: Exclusive agreement to co-market and co-promote Seq-MRD in hematologic-focused hospitals and clinics across China
Genoox	Aspira Women's Health	<ul style="list-style-type: none"> Objective: Develop AI and machine learning-driven technologies to improve molecular diagnosis and creation of treatment plans for conditions affecting women in early disease stages Dynamic: Create new tests backed by data analysis by bringing together Aspira's biobank and algorithms with Genoox's bioinformatics platform
Twist Bioscience	Centogene	<ul style="list-style-type: none"> Objective: Develop and commercialize sequencing assay kits for rare disease genetic testing. Dynamic: Assays to = combine Centogene's experience in rare disease diagnostics with Twist's target enrichment capabilities for NGS library preparation
Cue Health	Google Cloud	<ul style="list-style-type: none"> Objective: Add respiratory viral variant sequencing and tracking to Cue Integrated Care platform Dynamic: Cue to build Google Cloud's AI, machine learning, analytics, and privacy and security tools into its platform, which includes its Cue Health Monitoring System and rapid molecular COVID-19 test

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■ DX Deals: Becton Dickinson Lands \$40.3 Million BARDA Contract to Develop 510(k)-Worthy COVID-19 Tests, from page 15

Partner 1	Partner(s) 2+	Deal Summary
OncoDNA	Sophia Genetics	<ul style="list-style-type: none"> Objective: Improve analysis and interpretation of genomic profiles Dynamic: OncoDNA to customize its OncoKDM genomic interpretation platform to work with Sophia's DDM genomic analytics technology

DISTRIBUTION, SALES & MARKETING AGREEMENTS

Product Owner	Distributor	Deal Summary
Tasso	InnoVero	<ul style="list-style-type: none"> Products: Tasso's blood collection devices for anti-doping testing Territory: Worldwide Exclusive
Deep Bio	Healthcare Konnect	<ul style="list-style-type: none"> Products: Deep Bio's AI-based DeepDx Prostate software Territory: Switzerland, Morocco, Algeria, Egypt, Tunisia
Parse Biosciences	Decode Science	<ul style="list-style-type: none"> Products: Parse's single-cell RNA-seq solutions Territory: Australia and New Zealand Exclusive
Clever Culture Systems	Remel (subsidiary of Thermo Fisher Scientific)	<ul style="list-style-type: none"> Products: CCS' APAS Independence automated culture screening and interpretation system Territory: US Five-year exclusive agreement
Mawi DNA Technologies	Fujifilm Wako Pure Chemical	<ul style="list-style-type: none"> Products: Mawi's iSWAB biosampling products Territory: Japan Fujifilm to be an authorized Japanese distributor of iSWAB line including iSWAB Microbiome-EL sample collection tubes
Euformatics	Singapore All Eights	<ul style="list-style-type: none"> Products: All of Euformatics' products, including Omnomics interpretation and validation software for next-generation sequencing Territory: Malaysia
Euformatics	Biomedic	<ul style="list-style-type: none"> Products: All of Euformatics' products, including Omnomics interpretation and validation software for next-generation sequencing Territory: Vietnam

LICENSES

Licensor	Licensee	Deal Summary
Atreca	Bill & Melinda Gates Medical Research Institute (MRI)	Oncology biotech Atreca licenses its preclinical monoclonal antibody for potential treatment of malaria

Licensor	Licensee	Deal Summary
Inscripta	Hunterian Medicine	Gene editing and gene therapy company Hunterian gets nonexclusive access to Inscripta's MAD7 CRISPR nuclease enzyme for use in developing human therapeutics
MilliporeSigma	Cellecta	Merck KGaA firm licenses CRISPR-Cas9 technology to functional genomics products and services provider

GOVERNMENT CONTRACTS

Contractor	Govt. Agency	Contract Summary
Quest	Texas Department of State Health Services	Quest to provide COVID-19 testing for K-12 schools in Texas via its labs in the Houston and Dallas-Fort Worth areas
Eurofins Genomics US	US Department of the Air Force and Department of Health and Human Services	\$30 million contract to build a new production facility and to expand manufacturing capacity for reagents used in COVID-19 diagnostic tests
OraSure Technologies	US Department of Defense	\$109 million contract for manufacturing scale-up for OraSure's InteliSwab rapid SARS-CoV-2 antigen assays

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OCTOBER 2020
Emerging Tests: COVID-19 Antigen Tests Are Ready for Mass Utilization but Antigen Test Reporting is Not
It will take something on the order of 200 million COVID-19 screening tests per month, as opposed to the 25 million being performed currently, to safely respond to the U.S. estimate a new surge from Duke University. Because of their low costs, scalability and speed, antigen tests may play a crucial role in meeting this unprecedented level of demand, particularly in nursing home, educational and workplace settings. However, if antigen testing is to be the answer, there is one significant problem that will need to be addressed: lack of reliable and consistent test data reporting.
The Promise of Antigen Testing
What the country and world need right now are point-of-care tests that can deliver accurate results at cost-effective prices that can be

INSIDE THIS ISSUE
New studies speak to Standardize SARS-CoV-2 antibody tests
FDA Watch: Agency to Provide Emergency Clearance for Multi-Analyte Respiratory Panels
TOP OF THE NEWS: CDC Withdraws Recommendation of Testing for Asymptomatic Individuals after Close Exposure to COVID-19
GENETIC TESTS: New Guidelines Advise Against Using Polygenic Risk Scores for Routine Patient

Testing Strategy: New Study Shows Saliva-Based

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November 2020

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COMPLIANCE Perspectives: How to Create a Legally Sound Substance Abuse Policy
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MODEL TOOL: Model Substance Abuse and Fitness for Duty Policy
FDA WATCH: FDA Pulls the Plug on EUA Review of COVID-19 LDTs
NEWS: CDC Cautions Down on Providers Who Don't Provide Individuals Timely Access to PPE

So much for the pandemic's dulling the momentum of federal fraud enforcement. Dubbed "Operation Rubber Stamp," the new nationwide enforcement action revealed by the Department of Justice (DOJ) on Sept. 29 is the largest "take-down" in Department history involving 58 federal districts, 345 defendants, including over 100 doctors, nurses and other licensed medical professionals, and \$6 billion in false claims. And, while not necessarily the primary target, medical labs have been pulled in to the "Rubber Stamp" dragnet.
The Takedown Target
Of the \$6 billion in false and federal claims submitted to federal health care programs and private insurers involved

Compliance Perspectives: How to Create a Legally Sound Substance Abuse Policy
Bottom Line on Top: Make it all about fitness for duty, rather than zero tolerance

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Whatfieldnews: California Case Shows

Special Report: The 5 Things Labs Need to Know about the Biden COVID-19 Testing Plan
Testing labs on the front lines of the COVID-19 battlefield are getting federal reinforcements. And it's not just money. The new administration is taking an entirely new line of attack that differs from the approach of its predecessor in almost every conceivable way. Perhaps the starkest contrast is with regard to urgency, with the new president unveiling his COVID-19 testing strategy on his very first day in office. Here's a quick overview of the five key elements of the Biden plan, aka, National Strategy for COVID-19 Response and Pandemic Preparedness.
1. Provide More Money
Let's start with money. The administration's proposed \$3.9 trillion American Rescue Plan includes \$50 billion to expand COVID-19 testing by providing funding to purchase rapid tests, expand lab capacity and support regular testing efforts of schools and local governments.

Contact Andrea for details on this special offer
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