

Pharma IT

Mind's role in therapeutics, wellness means opportunity for cognitive assessment technology

FIRST ANALYSIS QUARTERLY INSIGHTS

Integrative insights on emerging opportunities

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Joe Munda has worked in finance and investment for 15 years and joined First Analysis in 2015. He works with entrepreneurs as an investor and as an advisor on growth transactions to help build leading businesses in healthcare technology. He has played a key role in building First Analysis's franchises in drug development technology and medical technology and has

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About First Analysis

First Analysis has a four-decade record of serving emerging growth companies, established industry leaders and institutional investors in emerging high-growth segments in technology and healthcare, both through its venture capital investments and through First Analysis Securities Corp. (FASC), which provides investment banking and related services. FASC is a FINRA-registered broker-dealer and member SIPC. First Analysis's integrative research process underpins all its efforts, combining 1) dynamic investment research on thousands of companies with 2) thousands of relationships among executives, investors and other key participants in our focus areas, yielding a deep, comprehensive understanding of each sector's near-term and long-term potential.

First Analysis

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PHARMA IT

Mind's role in therapeutics, wellness means opportunity for cognitive assessment technology

- The increasing burden and costs associated with Alzheimer's disease and other neurodegenerative diseases have made early diagnosis and intervention a national priority. However, conducting clinical trials to develop therapies for diseases like Alzheimer's is particularly challenging, contributing to higher costs than for many other conditions. Cognitive assessment technology is an important solution to this challenge.
- Applications for cognitive assessment technology extend beyond neurodegenerative diseases. Trial sponsors, regulators and physicians are increasingly interested in measuring and monitoring cognitive function during the drug development process to assess safety and risk for a broad spectrum of drugs. We think digital cognitive assessments, which trial sponsors have recently adopted out of necessity (often due to the pandemic) will continue to grow in popularity.
- We highlight some of the companies providing cognitive assessment technology to trial sponsors for a variety of applications. Their capacity to improve understanding of cognition in healthcare offers enormous promise for technology providers, pharmaceutical companies, and quality of life.

ALZHEIMER'S AND OTHER NEURODEGENERATIVE DISEASES DOMINATE THE COGNITIVE HEALTH CHALLENGE

Cognition is defined as the mental action or process of acquiring knowledge and understanding through thought, experience and the senses. It involves various brain functions and processes such as knowledge, attention, memory, language, reasoning, judgement, comprehension, decision making and visuospatial function. Cognitive impairment refers to persistent deficits in the brain's ability to function effectively. Cognitive impairment can have significant impact not only on the daily lives of patients but also their families. Depending on severity, signs of cognitive impairment, such as memory loss, confusion and difficulties carrying out routine dayto-day tasks, can be pronounced or subtle. Cognitive impairment is associated most notably with neurodegenerative diseases such as Parkinson's disease, amyotrophic lateral sclerosis, Huntington's disease and Alzheimer's disease.

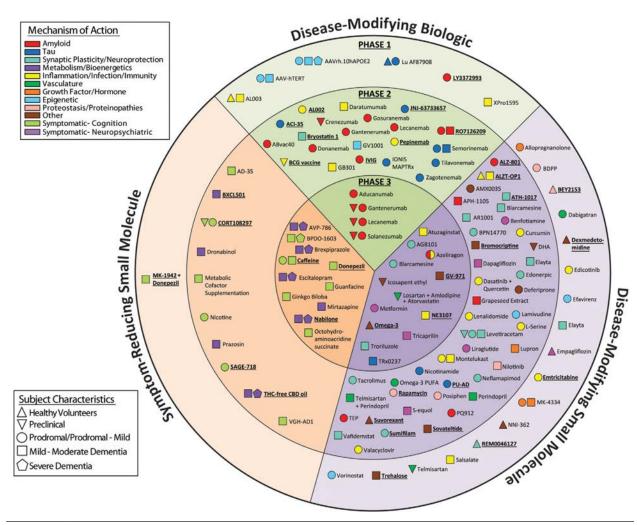
Alzheimer's, the most common neurodegenerative disease, is a progressive brain disorder that slowly destroys memory and thinking skills, and eventually the ability to carry out simple tasks. According to statistics from the Alzheimer's Association, an estimated

6.2 million Americans age 65 and older are currently living with Alzheimer's. In addition to being the sixth-leading cause of death in the United States, it is costly. The current total national cost of caring for patients with Alzheimer's other dementias is about \$355 billion annually, not including an estimated \$257 billion in unpaid caregiving. Without progress, the number of patients suffering from Alzheimer's is expected to double to about 13 million by 2050, with annual costs projected to eclipse \$1 trillion.

BEYOND HARDWARE AND CHEMISTRY: KEY ROLE FOR COGNITIVE ASSESSMENTS IN THE NEURODEGENERATIVE CHALLENGE

The increasing burden and rising costs associated with Alzheimer's have made early diagnosis and intervention an urgent national priority. According to the Alzheimer's Association, advances in early diagnosis could save the United States an estimated \$7.9 trillion. The problem is that Alzheimer's is difficult to diagnose. There is no single test for Alzheimer's. Physicians use a variety of tools to help diagnose the disease such as imaging (magnetic resonance imaging, positron emission tomography scans and single-photon emission computed tomography scans with specific radiotracers) and cerebrospinal fluid tests for various disease-as-

TABLE 1: 2021 Alzheimer's drug development pipeline



Source: Wiley Periodicals, May 2021. Alzheimer's & Dementia: Translational Research & Clinical Interventions

sociated proteins such as amyloid or tau. Unfortunately, neuroimaging and biomarker-based detection can be costly or inaccessible for patients.

As a result, cognitive assessments are being used to assist with early screening, diagnosis, treatment selection, patient monitoring and clinical research. Cognitive assessments are tests used to measure a patient's ability to perform tasks and establish the severity of cognitive impairments over time. Cognitive assessments are typically administered in a battery of tests assessing domains including memory, attention, processing speed, visuospatial function and problem-solving. Traditionally, cognitive assessments are performed on-site in a clinical setting with pencil and paper or on a computer; however, the on-site assessment model tends to be burdensome for patients who are typically elderly and already struggling with mobility issues. In addition, they tend to be time consuming, requiring a trained specialist to administer, score and report on the results.

COMPELLING CASE FOR COGNITIVE ASSESSMENTS IN DRUG DEVELOPMENT

It takes an average of \$2.6 billion, including cost of failures, and 10 to 15 years to discover, develop and win approval for a new drug. Additionally, only one of every 10 drugs that starts trials ends up being approved by the Food and Drug Administration (FDA). Alzheimer's drug development costs are substantially higher than for other therapeutic areas, costing an average \$5.6 billion, including the cost of failures, and taking over 13 years from study start to approval by the FDA. Between 1998 and 2017, there were 146 unsuccessful clinical trials for Alzheimer's-

related therapies. In that same time frame, only four new drugs were approved, none of which focused on Alzheimer's underlying pathophysiology but rather on treating symptoms. Despite these setbacks, pharmaceutical companies remain committed to finding new therapies. As of January 2021, there were 126 drugs in 152 trials assessing new therapies for Alzheimer's.

Several factors make conducting Alzheimer's trials particularly challenging, contributing to the higher cost: Patients who are candidates for Alzheimer's drug trials often refuse an invasive lumbar puncture to assess levels of proteins in the cerebrospinal fluid, and imaging can be expensive and difficult to schedule, especially during the pandemic. This makes it hard to screen, enroll and retain Alzheimer's trial participants, leading to long and expensive clinical trials.

Cognitive assessments are an important tool in overcoming this challenge. Trial sponsors can use cognitive assessments in place of or in conjunction with physical assessments to make screening, enrolling and stratifying patients, detecting adverse events, and measuring outcomes more efficient and less costly. Cognitive assessments become even more powerful when combined with technology to automate and administer them remotely. It can be challenging for clinical trial sites to hire and train qualified raters needed for manually administered tests, and it can be difficult to get Alzheimer's patients to a centralized trial site. Administering cognitive assessments in decentralized clinical trials (DCTs) addresses these challenges. Decentralized trials are trials conducted either completely or partially outside traditional trial-site settings using digital tools that enable direct-to-patient support and remote monitoring. These digital tools include tele-

Table 2: Cost and duration of each aspect of Alzheimer's drug development

Stage of process	Duration (months)	Capitalized cost including cost of failures (billions)	Cumulative out-of-pocket costs for candidate only (at end of each stage, millions)
Preclinical	50.1	\$1.65	
Phase I	12.8	\$1.19	\$71
Phase II	27.7	\$1.04	\$126
Phase III	50.9	\$1.79	\$413
FDA	18.0	\$0.02	
Total	13.3 years	\$5.69	

Source: Alzheimer's & Dementia: Translational Research & Clinical Interventions, 2018: *The price of progress: Funding and financing Alzheimer's disease drug development.*

medicine, wearable devices and sensors, and electronic clinical outcome assessments (eCOAs).

The FDA describes a clinical outcome assessment (COA) as an assessment that directly or indirectly measures how patients feel or function and can be used to determine whether a drug has been demonstrated to provide a treatment benefit. Historically, paper was predominantly used to collect COA data in clinical trials, but electronic COA, or eCOA, has become the preferred method of data collection, particularly when COA data is being used as the primary or secondary endpoint for a clinical trial. Types of COAs include:

- Patient-reported outcome (PRO): A
 measurement based on a report that
 comes directly from the patient about
 the status of a patient's health condition,
 without amendment or interpretation of the
 patient's response by a clinician or anyone
 else.
- Observer-reported outcome (ObsRO): A
 measurement based on a report of observable signs, events or behaviors related to
 a patient's health condition by someone
 other than the patient or a health professional. Generally, observer-reported outcomes are reported by a parent, caregiver
 or someone else who observes the patient in daily life, and they are particularly useful for patients who cannot report for themselves.
- Clinician-reported outcome (ClinRO):
 A measurement based on a report that comes from a trained healthcare professional after observation of a patient's health condition. Most clinician-reported outcome measures involve clinical judgment or interpretation of the observable signs, behaviors or other manifestations related to a disease or condition.
- Performance outcome (PerfO): A measurement based on standardized tasks undertaken by a patient according to a set of instructions. A performance outcome assessment may be administered by an appropriately trained person or completed by the patient independently. Cognitive assessments fall into this bucket.

Using technology such as smartphones and tablets to remotely assess cognition brings some risks. Research has shown that test anxiety can have a significant effect on cognitive performance, and older patients using remote technology to complete cognitive assessments may experience anxiety and stress if they don't understand test instructions, struggle to complete a task, or are generally uncomfortable using technology. Additionally, participants may be embarrassed about their declining cognitive abilities and perform differently than they would in an on-site face-to-face testing environment, or they may be more tempted to give up rather than risk a wrong answer or forgetfulness. Caregivers may unintentionally interfere by repeating words or instructions or directing a participant's attention (such as by pointing or signaling); indeed, the caregiver's presence alone may affect participant performance. Nonetheless, we think digital cognitive assessments, which trial sponsors have recently adopted out of necessity, often due to the pandemic, will continue to grow in popularity while a subset of more difficult and sensitive cognitive assessments will remain on-site.

ADUHELM ALZHEIMER'S APPROVAL A VANGUARD OF WIDENING OPPORTUNITY FOR COGNITIVE ASSESSMENTS

In June, the FDA approved Aduhelm, the first disease-modifying therapy for Alzheimer's. It was the first new treatment for Alzheimer's to be approved by the FDA in nearly 20 years and is the first therapy that targets the fundamental pathophysiology of the disease rather than the symptoms. Approvals of the first drug in a new category tend to invigorate the field, increase investment in new treatments and encourage greater innovation. To the extent this is true of Aduhelm, we expect adoption of cognitive assessment technology to gain further momentum.



Aduhelm, jointly developed by Biogen (BIIB) and publicly traded Japanese pharma company Eisai, is a human-made antibody designed to remove toxic clumps of the protein

TABLE 3: Cogstate Brief Battery

The Cognigram system uses the Cogstate Brief Battery, which has been used in over 1,000 research studies around the world and cited in hundreds of peer-reviewed publications. The battery (see below) consists of four tests, where a single playing card stimulus is presented in the center of the device screen. At the presentation of each playing card stimulus, the patient is required to respond either "YES" or "NO".



Detection test

"Has the card turned over?"

Main domain measured

Psychomotor function



Identification test

"Is the card red?"

Main domain measured

Attention



One card learning test

"Have you seen this card below?"

Main domain measured **Learning**



Detection test

"Is the card the same as the previous card?"

Main domain measured
Working memory

Source: Cogstate.

beta-amyloid, which is thought to drive the death of brain neurons in Alzheimer's patients. Australia-listed cognitive assessment technology provider **Cogstate** is a direct beneficiary of Aduhelm's approval. Cogstate is a neuroscience-focused provider of digital cognitive assessments used in clinical research and clinical treatment. Its Cogstate Brief Battery (CBB) is expected to be used for screening and monitoring Aduhelm candidates. Cogstate CEO Brad O'Connor notes, "Cogstate's solutions are about removing friction." In October 2020, Cogstate entered into an exclusive 10-year agreement with Eisai for the global development rights and exclusive commercialization rights of all cognitive function tests developed by Cogstate.

OPPORTUNITY FOR COGNITIVE ASSESSMENT TECHNOLOGY BEYOND ALZHEIMER'S

Current and future applications for cognitive assessment technology extend well beyond Alzheimer's. Trial sponsors, regulators and physicians are increasingly interested in measuring and monitoring cognitive function during drug development to assess safety and risk for a broad spectrum of drugs. Some drugs can exert a cognitive effect at any time across a patient's life. This includes not only central nervous system (CNS) drugs but also non-CNS therapies (oncology drugs, pain drugs, antihistamines, cardiovascular drugs including statins, AIDS drugs, and antimus-

carinics). For example, in 2012 a post-marketing surveillance study of statins uncovered several adverse effects tied to cognitive performance and psychological symptoms, including memory loss, amnesia, altered mood, irritability, sleep disruption and confusion. As a result, the FDA mandated warnings for all statin drugs for possible adverse effects on cognition.



BRAINBASELINE

Chemotherapy is often associated with cognitive impairment known as chemobrain. A recent study focused on the effects of physical activity and fatigue on cognitive performance in breast cancer survivors found that physical activity reduced fatigue and had a positive impact on cognition. The researchers used an innovative mobile platform from BrainBaseline that includes self-administered cognitive and motor assessments capable of detecting neurocognitive impairments. According to CEO Joan Severson, "Regardless of indication, BrianBaseline's platform provides trial sponsors with a novel quality-of-life understanding in the real world by capturing cognition in the wild."

In another example, BrainBaseline is developing digital biomarkers for Parkinson's disease through the Watch-PD clinical trial sponsored by the University of Rochester in collaboration with Biogen and Takeda. In our view, the observational study's design allows

Platform Overview - WATCH-PD Application

Apple Watch Application



The Apple Watch app enables collection of continuous accelerometer and gyroscope data and utilizes HealthKit data to acquire information on workouts, heart rate, step count, falls, and hours standing. In Parkinson's disease we are also utilizing the Apple Movement Disorders API to acquire continuous information on tremor and dyskinesia severity.

The Watch is also used as a interface to initiate instrumented motor tasks that engage sensors in the watch and a phone placed in a pouch in the lumbar region of the back

Patient-Reported Outcomes



Patient reported outcomes are collected contemporaneously with structured task data using a set of VAS and Likert questions, and include measures of mood, fatique, cognition, tremor, and bradykinesia

Cognition Tasks



Cognitive tests of frontal function were adapted from pencil paper standards and produce outcomes similar to these neuropsychological tests in addition to novel metrics derived from continuous data obtained through a patient's interaction with the touchscreen

Test	Data Collected
Trails A & B	Total time, errors, continuous x/y coordinates of touch (i.e., 'path')
Verbal Digit Symbol Substitution	Total correct, error, lossless voice data
Visual Spatial working Memory	Total Correct/Incorrect; Capacity estimates

Psychomotor Tasks



Psychomotor tests include a fine motor task based on the grooved pegboard and an alternating finger tapping and allow collection of both standard outcomes and continuous data obtained through interaction with the tou

Test	Data Collected
Fine Motor	Total time, total error, continuous x/y coordinates of touch
Alternating Finger Tapping	Total number of taps, intertap interval,, total errors, continuous x/y coordinates of touch interaction

Speech Tasks



Speech tasks were modeled after standard clinical speech assessments and collect lossless sound files to allow acoustic analysis

Test	Data Collected
Sustained Phonation	Phonation Duration, lossless voice data
Verbal Articulation	Lossless voice data
Sentence Reading	Time to complete, lossless voice data

Instrumented Motor Exam



Motor tests were designed to measure common symptoms of Parkinson's Disease that are highly affected as the disease progresses and affect activities of daily living.

Test	Data Collected
Walking	Raw and calibrated accelerometer, gyro, and magnetometer data, pitch, roll, yaw
Posture	Raw and calibrated accelerometer, gyro, and magnetometer data, pitch, roll, yaw
Tremor	Raw and calibrated accelerometer, gyro, and magnetometer data, pitch, roll, yaw

ADPD I 2019 I Lisbon, PT

Source: Biogen, BrainBaseline.

for more unbiased real-world measurement across the different populations who suffer from Parkinson's disease and the variety of symptoms they exhibit. The study is expected to be completed in 2022. Once validated, the biomarkers are expected to be used to help assess other movement and mobility disorders.



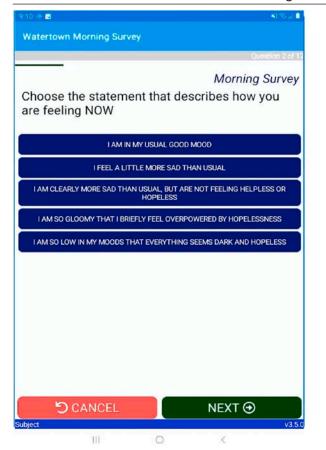
Another company, eClinical solutions provider **ERT**, has partnered with Cogstate to expand ERT's industry-leading eCOA solution with digital cognitive endpoint measurement to enhance safety and efficacy assessment in clinical trials that include capabilities for at-home testing. (The Cogstate-Eisai agreement specifically excludes clinical trials.)

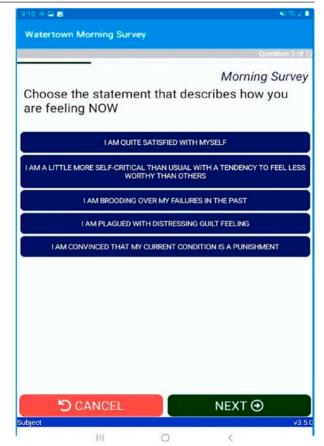


EMA Wellness focuses on ecological momentary assessments (EMA). According to EMA Wellness Chief Scientific Director Phil Harvey, "The company's technology allows for fundamentally better outcomes by capturing the variability in trial participant be-

haviors." EMAs collect data in real time and in real-world settings to avoid retrospective biases and memory distortions, to collect ecologically valid data, and to study behavioral processes over time. An EMA enables more frequent sampling (often multiple times a day), so time-series analysis can be performed, providing a deeper understanding of processes at work versus static snapshots at distant time points. The premise is that single-time-point assessments fail to capture variability in human cognitive performance affected by a host of factors, including mood, stress and time of day. EMAs have been used in numerous clinical trials, including to identify the best predictors of substance use, a way to identify anxiety symptoms and behaviors, and as a way to track elderly people's activities. For example, the company's EMA smartphone app was recently used to track the course of symptoms in a depression trial. Trial participants received daily queries throughout the screening and treatment phases of the study. Participants were queried twice daily, including on the in-person clinic visit days.

TABLE 5: EMA Wellness Watertown Morning Survey





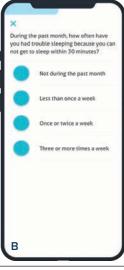
Source: EMA Wellness.



Gamification can be an important element of cognitive assessment technology. Gamification involves extracting the elements of gameplay that trial participants find compelling and using them to drive trial engagement and compliance without undermining scientific value. Datacubed Health's mobile eCOA platform Linkt incorporates behavioral science tools such as reward systems, progress and feedback to provide participants with an intrinsically motivating experience that promotes participant retention and compliance in longitudinal studies. Datacubed Health Chairman and founder Paul Glimcher explained, "It is a basic tenet of user experience science that, if the technology can be well aligned with a participant's identity, it can significantly improve the quality and timeliness of compliance." Linkt has a library of cognitive assessments, can collect audio recordings of patients performing speech and language tasks, and includes a survey builder. The app also integrates passive data, including global positioning system and pedometer data.

TABLE 6: Examples of Linkt app mobile user interface







Source: Datacubed.



Signant Health's SmartSignals eCOA is described as a validated and flexible cognitive assessment platform designed for repeated use in clinical trials. It comprises a range of tests assessing essential cognitive domains relevant to everyday life activities such as attention, working memory, episodic memory and executive function.

CAMBRIDGE COGNITION

London-traded Cambridge Cognition has developed a suite of computerized neuropsychological tests called the Cambridge Neuro-psychological Test Automated Battery (Cantab). Cantab is widely used in academic, clinical and pharmacological research and has been published in over 2,000 peer review papers. Cantab tests include a suite of cognitive assessments measuring aspects of cognitive functioning in therapeutic areas including attention and psychomotor speed, executive function, memory, emotion and social cognition. Users initially administered Cantab on personal computers, but the company now offers a tablet-based Cantab mobile application. Cambridge Cognition also offers an online platform for trial recruitment that pre-screens patients using its cognitive assessment instruments.

$THREAD^{\scriptscriptstyle{\mathsf{M}}}$

Decentralized clinical trial platform provider **Thread** offers virtual visits via telehealth technology that enables trial staff to instruct, administer and monitor assessments remotely. Thread's platform is agnostic to the cognitive assessment being used during the trial and can partner with vendors offering their own proprietary battery of tests. According to Thread CEO John Reites, "It's not the what, but the how it's being captured" that's critical to Thread.



eClinical solutions provider WIRB-

Copernicus Group (WCG) has acquired several cognitive assessment technology companies. In May 2017, the company acquired MedAvante and ProPhase, and in July 2021, it acquired VeraSci (formerly NeuroCog), a cognition and clinical assessment solutions company. Via its Pathway technology platform, VeraSci enables remote collection of high-quality data that can be used to assess symptoms, cognition and functional capacity in a wide range of therapeutic trials including CNS-related trials.

RICH OPPORTUNITY FOR COGNITIVE ASSESSMENT TECHNOLOGY PROVIDERS AND SOCIETY AS A WHOLE

Cognitive assessment technology makes it easier and faster to achieve improved understanding of cognition to advance healthcare. Prospects for increased use of cognitive assessment technology in drug development, and ultimately in healthcare more broadly, offer enormous promise for technology providers, pharmaceutical companies, and quality of life throughout our society.

eClinical index return far ahead of Nasdaq, S&P 500; commercialization index lags all

The First Analysis eClinical Index appreciated 42% over the one-year period ended Sept. 28, somewhat off its high during the period of 54%, while the First Analysis Commercialization Index ended the period with only a 10% return, well below its 24% peak during the period. Both Nasdaq and the S&P 500 ended the period with about 30% returns.

All but two of the eClinical stocks were up over the period. Paris-traded Dassault Systémes, which accounted for nearly half the eClinical index's capitalization as of Sept. 28, 2020, contributed more than a third of the index's gain as it appreciated 40% during the period. Iqvia (IQV) contributed another third of the gain as it appreciated 56%. The two largest gainers were Australia-traded

eClinical/commercialization public comparables*

(\$ in millions)		Revenue growth				Enterprise value /			
	LTM	2020A-	2021E -2022E	LTM gross	LTM EBITDA	Revenue		EBITDA ¹	
Company	revenue	2021E		margin	margin	2021E	2022E	2021E	2022E
Commercialization									
Clarivate (CLVT)	\$1,614.0	45.5%	6.6%	67.2%	33.6%	10.46x	9.80x	23.4x	21.2x
Informa (LSE: INF)	\$2,079.5	12.2%	24.6%	29.1%	14.8%	5.59x	4.49x	20.8x	13.9x
Model N (MODN)	\$183.4	21.8%	10.4%	56.1%	(1.1%)	5.83x	5.29x	NMF	41.5x
OptimizeRx (OPRX)	\$51.8	40.2%	28.6%	55.6%	7.5%	20.00x	15.56x	NMF	NMF
PaySign (PAYS)	\$20.0	25.3%	36.7%	31.3%	(44.6%)	4.44x	3.25x	NMF	19.3x
Phreesia (PHR)	\$179.6	33.3%	21.9%	62.8%	(20.1%)	13.42x	11.01x	NMF	NMF
Veeva Systems (VEEV)	\$1,663.4	25.2%	18.9%	72.6%	28.9%	22.64x	19.05x	NMF	47.2x
Wolters Kluwer (ENXTAM: WKL)	\$5,359.7	1.9%	3.9%	71.0%	30.1%	5.55x	5.34x	17.8x	16.8x
Averag	e \$1,393.9	25.7%	18.9%	55.7%	6.1%	10.99x	9.22x	20.7x	26.7x
Media	n \$898.7	25.2%	20.4%	59.5%	11.2%	8.15x	7.57x	20.8x	20.3x
eClinical									
Cambridge Cognition (AIM: COG	i) \$9.3	50.1%	6.9%	80.4%	(9.1%)	4.37x	4.08x	NMF	NMF
Centogene (CNTG)	\$264.2	50.3%	(57.8%)	26.8%	(0.4%)	1.19x	2.83x	NMF	NMF
Certara (CERT)	\$261.8	18.6%	16.7%	57.4%	4.0%	19.35x	16.58x	NMF	45.8x
Cogstate (ASX: CGS)	\$32.7	NA	NA	53.5%	13.8%	NA	NA	NA	NA
Dassault (ENXTPA: DSY)	\$5,420.6	8.0%	9.8%	83.4%	21.7%	13.55x	12.33x	36.5x	33.8x
Icon (ICLR)	\$3,191.3	94.4%	43.8%	28.4%	17.5%	3.69x	2.56x	21.70x	14.8x
Iqvia Holdings (IQV)	\$12,931.0	22.0%	8.2%	33.6%	17.2%	4.44x	4.10×	20.5x	18.6x
Ixico (AIM: IXI)	\$13.7	NA	NA	67.1%	13.3%	NA	NA	NA	NA
LifeSci Acquisition II (LSAQ)	-	-	-	-	-	-	-	-	-
PPD (PPD)	\$5,551.9	23.3%	7.0%	66.3%	16.6%	3.53x	3.30x	19.1x	17.3×
Research Solutions (RSSS)	\$31.4	NA	1.3%	32.0%	(0.6%)	1.73x	1.71x	NMF	NMF
Schrödinger (SDGR)	\$120.7	21.3%	52.9%	51.7%	(68.6%)	28.12x	18.39x	NMF	NMF
Simulations Plus (SLP)	\$46.2	6.7%	14.2%	77.3%	35.9%	17.17×	15.04x	NMF	42.4x
Syneos Health (SYNH)	\$4,730.4	18.6%	8.7%	23.8%	13.4%	2.42x	2.22x	16.7x	14.9x
Averag	e \$2,508.1	31.3%	10.2%	52.4%	5.7%	9.05x	7.56x	22.9x	26.8x
Media	n \$261.8	21.6%	8.7%	53.5%	13.4%	4.37x	4.08x	20.5x	18.6x

Source: Capital IQ, First Analysis.

Notes: * Public comparable company data shown above is as of Sept. 28, 2021.

(1) EBITDA multiples less than 0 and greater than 50 labeled "NMF".

Cogstate, up 229%, and London-traded Cambridge Cognition, up 194%, both of which we discuss in the introduction to this report.

Five of the eight pharma commercialization stocks were up over the period. Wolters Kluwer, which accounted for about a quarter of the index's total capitalization as of Sept. 28, 2020, contributed more than half the index's gain as it appreciated 24%. The two largest gainers were OptimizeRX (OPRX), up 238%, and Phreesia (PHR), up 107%.

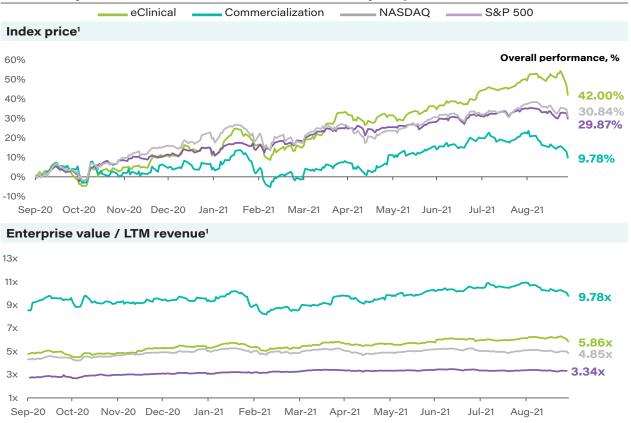
The eClinical index's enterprise value multiple of trailing-12-month revenue ended the period at 5.9, up slightly from the 5.6 ending multiple we reported in April. The commercialization index's multiple ended the period at 9.8, up from the 8.5 ending multiple we reported in April. Looking at enterprise value multiples of estimated 2022 revenue, the average and median multiples for the eClinical group were 7.6 and 4.1 as of Sept. 28, versus 8.2 and 3.7 in our April report, with the average 2022 estimated revenue growth rate decreasing to 10.2% from 16.2% in our April report. The average and median 2022 multiples for the

commercialization group as of Sept. 28 were 9.2 and 7.6, up from 8.1 and 6.5 in our April report, with the average 2022 estimated revenue growth rate increasing to 18.9% from 16.3% in our April report.

For the commercialization group, the metrics above reflect the removal of UDG Healthcare following its acquisition by private equity firm Clayton, Dubilier & Rice.

For the eClinical group, the metrics above reflect the removal of PRA Health Sciences following its acquisition by another eClinical group member, Icon (ICLR). We also added three companies: Centogene (CNTG), which has developed a global proprietary rare disease platform to accelerate the development of new orphan drugs based on its real-world data repository; London-traded Cambridge Cognition, a leader in cognitive assessment software used in clinical trials; and LifeSci Acquisition II (LSAQ), a special purpose acquisition company that is acquiring clinical trial software provider Science 37 and is expected to be listed under the ticker SNCE when the transaction is completed.

First Analysis eClinical/Commercialization Index 1-year performance



Source: Capital IQ.

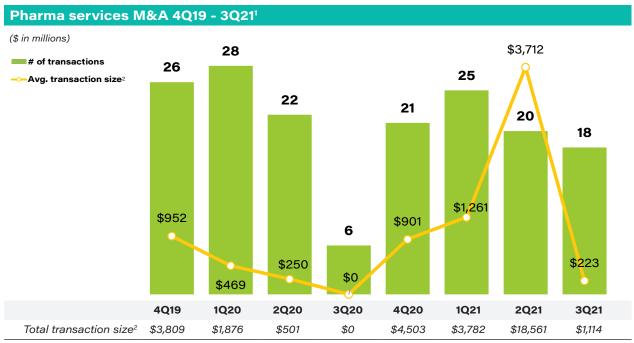
Notes: (1) eClinical/commercialization index performance is based on market cap weighted constituents. For the period from Sept. 28, 2020, through Sept. 28, 2021.

Pharma IT M&A activity for Q2 and Q3 within two-year range

We tally 20 notable pharma IT M&A transactions in Q2 and 18 in Q3, within the range over the past two years of six to 28 transactions per quarter. We highlight the following transactions.

In late May, Thoma Bravo agreed to acquire Greenphire in a transaction reported to be valued at about \$1.1 billion. Greenphire is a leader in global clinical trial financial process automation. Greenphire's solutions optimize clinical trial performance by streamlining payment and logistical workflows from sponsors and contract research organizations to sites and patients.

In early August, Certara (CERT), which provides biosimulation software and technology to accelerate drug discovery and development, announced it would acquire Pinnacle 21 for \$310 million in cash and stock. Pinnacle 21 provides software for preparing clinical trial data for regulatory submission. Its platform validates data quality and compliance with regulatory standards in major healthcare markets, including the United States, Japan and China. The acquisition furthers Certara's strategy to enhance its solution in order to increase the use cases for biosimulation and grow adoption of its end-to-end platform.



Source: Capital IQ, Pitchbook, First Analysis.

Notes: (1) 3Q21 includes reported transactions through Sept. 30, 2021.

(2) Average and total transaction size considers only those transactions with reported enterprise values.

Select recent M&A transactions (sorted by date of announcement)

(\$ in millions) Date	Target	Target business description	Buyer	Enterprise value (EV)	EV/ revenue
9/23/2021	ClinEdge	Patient recruitment and retention, marketing and creative design engagement services, patient travel coordination, trial management, staffing, and financial service solutions	Elligo Health Re- search	\$135.0	Undisclosed
9/22/2021	VitaLink Research	Network of clinical research centers	Velocity Clinical Research	Undisclosed	Undisclosed
9/17/2021	Prelude Dynamics	eClinical technology platform for human and animal health research	Canela Capital	Undisclosed	Undisclosed
9/7/2021	Ciitizen	Machine learning and AI technologies to Invitae (NVTA) abstract information from unstructured health records to advance understanding of diseases, match patients with clinical trials, and enable better care decisions		\$325.0	Undisclosed
8/18/2021	MicroConstants	Clinical and preclinical contract research organization providing services in the areas of method development, validation, and sample analysis for small molecules, macromolecules, biomarkers and metabolites	organization providing services in the areas of method development, validation, and sample analysis for small molecules, macromolecules,		Undisclosed
8/17/2021	SignalPath	Cloud-based software for clinical research	Verily	Undisclosed	Undisclosed
8/5/2021	Pinnacle 21	Software consulting company specializing in data integration, business intelligence, and data management solutions	Certara (CERT)	\$310.0	10.0x
8/3/2021	Experien Group	Regulatory, quality, clinical, and data manage- ment consulting services for the medical device industry	Veranex	Undisclosed	Undisclosed
8/2/2021	Clinlogix	Clinical research organization providing clinical trial management services to pharmaceutical, biotechnology, and medical device industries	Namsa	Undisclosed	Undisclosed
7/26/2021	VeriSci	Endpoints and clinical outcome assessments, eClinical software, HEOR consulting, and language and translation services	WCG Clinical	\$330.0	11.0x
7/20/2021	Health Decisions	Provides clinical research services	Premier Research	Undisclosed	Undisclosed
7/15/2021	BioPharma	Contract research organization conducting clinical research trials for pharmaceutical, biotechnology, and medical device companies worldwide	Think Research	\$44.6	Undisclosed
7/15/2021	Canadian Phase Onward	Clinical research organization providing clinical studies, trial recruitment, and management services	MCI Onehealth	Undisclosed	Undisclosed
7/12/2021	Sterling Research Group	Provides clinical research services	Meridian Clinical Research	Undisclosed	Undisclosed
7/8/2021	Heart Imaging Technologies	Web-based medical image management tech- nology and services	Intelerad	Undisclosed	Undisclosed
7/6/2021	Pyxant Labs	Bioanalytical contract research organization, provides analytical research, development, and validation services to support early stage drug discovery, preclinical studies, and clinical trial sample analysis	nt, and e drug		Undisclosed
7/2/2021	Parexel	Biopharmaceutical outsourcing company pro- viding clinical research and logistics, medical communications, consulting, and technology products and services for pharmaceutical, biotechnology, and medical device industries worldwide	EQT Partners; Goldman Sachs	\$8,500.0	4.0x
7/1/2021	Intrinsic Imaging	Medical imaging core lab that offers compre- hensive services to support Phase I-IV clinical trials and Class I, II, III medical device trials	WCG Clinical	\$92.1	Undisclosed
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Select recent M&A transactions (sorted by date of announcement)

(\$ in millions) Date	Target	Target business description	Buyer	Enterprise value (EV)	EV/ revenue
6/16/2021	Quartesian	Contract research organization providing clinical development services to pharmaceutical, biotechnology, and medical device companies in the U.S. and internationally	Summit Partners	Undisclosed	Undisclosed
6/9/2021	Datavant	Facilitates and manages the movement of health information to help clients manage health information and streamline processes	Ciox Health	\$7,000.0	Undisclosed
6/8/2021	Root Health	AI virtual assistant for clinical research to improve clinical study recruitment and retention	Elligo Health Re- search	Undisclosed	Undisclosed
6/2/2021	CardioLabs	Provider of holter and arrhythmia diagnostic management services	AliveCor	Undisclosed	Undisclosed
5/26/2021	Greenphire	Clinical trial payment solutions for sponsors, contract research organizations and research sites	Thoma Bravo	\$1,100.0	Undisclosed
5/20/2021	Clinical Outcome Solutions	Clinical outcomes assessment research services committed to continuous and dedicated support across all facets of clinical outcomes research that informs patient care value decisions	GHO Capital, Val- idant	Undisclosed	Undisclosed
5/13/2021	Summit Research Network	Medical research and clinical trial services	Headlands Re- search	Undisclosed	Undisclosed
5/11/2021	The Evanston Group	Life sciences consulting firm providing individu- al consultants and teams to life sciences' most complex and challenging projects in the United States	EG Life Sciences	Undisclosed	Undisclosed
5/11/2021	The Avoca Group	Clinical research and consulting services in the areas of relationship management, research, training and identifying	WCG Clinical	\$44.0	Undisclosed
5/7/2021	Science 37	Decentralized clinical trial operating system to facilitate universal participation in clinical trials for patients and providers	LifeSci Acquisition II (LSAQ)	\$1,050.0	43.8x
4/29/2021	PulsePoint	Programmatic advertising platform for brand engagement	Internet Brands	Undisclosed	Undisclosed
4/28/2021	Clinipace	Clinical research organization that provides services to venture-backed, mid-tier, and strategic pharmaceutical, biotechnology and medical device companies in the U.S. and internationally	dMed Undisclose		Undisclosed
4/26/2021	Aptitude Health	Healthcare market insights and strategic services to help translate clinical development into commercial success and cancer treatments	Linden Capital Partners	Undisclosed	Undisclosed
4/7/2021	Veristat	Clinical research organization supporting clinical trials for pharmaceutical, biotechnology, and medical device companies	WindRose Health Investors	Undisclosed	Undisclosed

Source: Capital IQ, First Analysis.

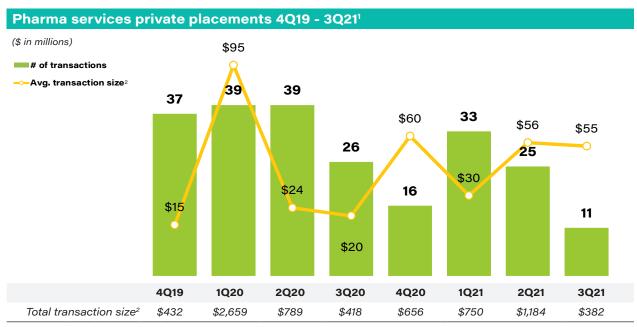
Pharma IT private placements slow in Q2, Q3

We tally 25 notable pharma IT private placements in the second quarter and 11 in the third quarter, following the 33 we reported in April for the first quarter. We highlight a few below.

At the end of June, 4G Clinical announced a \$230 million growth equity investment by Goldman Sachs Asset Management. First Analysis had invested in 4G Clinical at the end of 2019 and successfully exited its investment as part of this transaction. 4G Clinical provides randomization and trial supply management services for pharmaceutical companies and clinical research organizations worldwide. Its fully cloud-based, 100% configurable and flexible solution uses natural language processing to accelerate clinical trials.

In early May, Florence raised \$80 million in a Series C round led by Insight Partners. Florence is a global leader in remote connectivity and electronic document workflow management for clinical trials, a critical tool for conducting decentralized trials.

Also in early May, Science 37 announced it would receive \$200 million in growth capital from institutional and strategic investors, including BlackRock, Lux Capital, Perceptive Advisors and Redmile Group, as part of its merger with publicly traded special purpose acquisition company LifeSci Acquisition II (LSAQ). Science 37 was one of the early developers of decentralized clinical trials, enabling workflow orchestration, evidence generation and data harmonization on a unified platform that connects telemedicine investigators, mobile nurses, remote coordinators, patient communities and connected devices.



Source: Capital IQ, Pitchbook, First Analysis.

Notes: (1) 3Q21 includes reported transactions through Sept. 30, 2021.

(2) Average and total transaction size considers only those transactions with reported enterprise values.

Select recent private placements (sorted by date of announcement)

(\$ in millions) Date	Company	Business description	Investors	Raise type	Amount raised	Total amount raised
9/30/2021	Clinical trial sites with monetary compensation, medication, study visits, and study-related tests and procedures		Sequoia Capital; Spark Capital; Felicis Ventures; ArrowMark Colorado; Thrive Capital; Casdin Capital; Dragoneer; Sound Ventures; Section 32	Series C	\$156.0	Undis- closed
9/23/2021	Elligo Health Research	Healthcare-enabling research orga- nization providing clinical research infrastructure services and technol- ogies	Noro-Moseley; NVP; Cerner (CERN); Morgan Stanley; Hatteras Venture; Ally Bridge; Syneos Health (SYNH); Shumway Capital; Piper Sandler	Series E	\$135.0	\$176.6
9/20/2021	Vodori	Software solutions that enable life sciences companies to simplify the creation, approval, and distribution of regulated content	Baird	Series A	\$7.5	Undis- closed
9/14/2021	Lightship	Enterprise level and direct-to-pa- tient clinical research solutions and services	Undisclosed	Venture	\$40.0	\$50.0
9/9/2021	Courier Health	Healthcare software solution that enables patient engagement for life sciences companies	Work-Bench	Seed	\$4.0	Undis- closed
8/31/2021	Ellipsis Health	Analytics solutions that combine patient speech and clinical data to predict patient health and well-being	SJF Ventures; Greycroft Partners; Khosla Ventures; Alumni Ventures; Gener- ator Ventures; Springtide Ventures; Gaingels; Able Partners; Luminous Ven- tures; What If Ventures; TIME Ventures	Series A	\$26.0	\$30.0
8/19/2021	Modality.ai	Artificial intelligence (AI)-based patient screening solutions	Relentless Pursuits Part- ners	Seed	\$2.1	\$2.1
8/12/2021	Winterlight Labs	Speech-based platform for detecting cognitive and mental diseases such as dementia and Alzheimer's disease	DG Daiwa Ventures	Venture	Undis- closed	Undis- closed
7/30/2021	Montrium	Cloud-based collaborative content management software for the life sciences industry that offers clinical solutions, regulatory solutions, and quality solutions	BDC Capital	Growth	\$2.0	Undis- closed
7/26/2021	83Bar	Patient activation platform that locates, educates, and navigates patients across pharma, device and diagnostic campaigns, and for both clinical trials and commercial clients	HealthQuest	Venture	Undis- closed	Undis- closed
6/29/2021	4G Clinical	Provides randomization and trial sup- ply management services for phar- maceutical companies and clinical research organizations worldwide	Goldman Sachs	Growth	\$230.0	\$259.3
6/24/2021	Infiuss Health	Clinical research platform	Y Combinator	Acceler- ator	\$0.1	\$0.1
6/9/2021	Datavant	Aggregates and analyzes biomedical data through machine learning to lower the time, cost, and risk of drug development	Goldman Sachs; Sixth Street	Venture	Undis- closed	Undis- closed
6/8/2021	<u>'</u>		Northpond Ventures; Polaris Venture Partners; Section 32; Zetta Venture Partners	Series A	\$15.0	\$18.3

Select recent private placements (sorted by date of announcement)

(\$ in millions) Date	Company	Business description	Investors	Raise type	Amount raised	Total amount raised
6/3/2021	Antidote Online healthcare platform intended to assist in clinical trials		LBO France; Merck Global Health Innovation Fund; Octopus Ventures; Smed- vig Capital	Later Stage VC	\$32.7	\$66.2
6/2/2021	Steel Therapeutics	Al-based drug discovery and development platform	ISA Ventures	Early Stage VC	\$0.4	\$0.4
5/17/2021	ArisGlobal	Intelligent cloud software solutions for life sciences research and develop- ment industries	Nordic Capital		Undis- closed	Undis- closed
5/11/2021	Aetion	Healthcare technology platform designed to offer real-world analytics and evidence	B Capital; Flare Capital Partners; Foresite Capital; NEA; Warburg Pincus	Later Stage VC	\$110.0	\$212.0
5/6/2021	Science 37			PIPE	\$200.0	NA
5/3/2021	CliniSpan Health	Online medical platform intended to involve the community in the process of clinical trial education and patient recruitment	Undisclosed	Seed Round	\$0.3	Undis- closed
5/1/2021	Genoox	Genomic analytics platform designed to translate complex genetic data into useful clinical information	Glilot Capital Partners; Infinity Medical Clinic; In- imiti; Sumitomo Chemical; Triventures	Later Stage VC	\$8.0	Undis- closed
4/30/2021	Yatiri Bio	Cutting-edge proteomics and bio- informatics tools for therapeutic discovery	Undisclosed	Early Stage VC	\$1.7	\$1.7
4/29/2021	Headlands Research	Network of clinical trial sites intended to improve the clinical trials process	Undisclosed	PE Growth/ Expansion	\$1.2	\$10.3
4/29/2021	Merit CRO	Research services intended to assist in the ophthalmology and respiratory subspecialties	Undisclosed	Later Stage VC	\$2.0	Undis- closed
4/28/2021	Florence Healthcare	Tools that enable management and monitoring of clinical trial data flow	Bee Partners; Flash- point; Fulcrum Equity Partners; Insight Partners	Series C	\$80.0	\$88.9
4/28/2021	Aetion	Science and analytics platform to as- sess real-world evidence from a range of sources	Warburg Pincus; NEA; Flare Capital; Foresite Capital; B Capital	Series C	\$110.0	\$212.0
4/27/2021	Curebase	Software for remote clinical trials	GGV Capital; Xfund; Bold Capital Partners	Series A	\$15.0	Undis- closed
4/22/2021	Datacubed Health	Electronic clinical outcome assess- ments for patients participating in clinical trials	Sterling Partners	Early Stage VC	\$8.8	\$30.0
4/21/2021	SiteBridge Research	Integrated research organization intended to reach further into the community and empower more physicians and patients to take part in and democratize clinical research	Health2047; UnitedHealth Group Ventures	Seed Round	\$3.0	\$3.0
4/16/2021	Lightship	Clinical research software designed to transform the clinical research landscape	Undisclosed	Early Stage VC	\$10.0	\$24.9

Select recent private placements (sorted by date of announcement)

(\$ in millions) Date	Company	Business description	Investors	Raise type	Amount raised	Total amount raised
4/15/2021	Medable	Cloud-based platform designed to get effective therapies to patients	GSR Ventures; Obvious Ventures; PPD (PPD); Proof; Sapphire Ventures; Streamlined Ventures	Later Stage VC	\$78.0	\$217.0
4/9/2021	Mendel Health	Al-based solution that helps doctors and patients find best diagnostic and treatment methods for their patient's medical conditions	BootstrapLabs; DCM Ventures; LaunchCapi- tal; Millennium TVP; Ol- ive Tree Capital; SOSV Investments; Zola Global Investors	Series A	\$18.0	\$20.3
4/5/2021	Strategikon Pharma	Software that synchronizes sponsor and provider outsourcing processes	Tech Coast Angels; Band of Angels; De Novo; Life Science Angels; Golden Seeds; Wing Venture; Alumni Ventures Group; Osage Venture Partners	Series A	Undis- closed	Undis- closed

Source: Capital IQ, Pitchbook, First Analysis.

eClinical/commercialization public comparables appendix*

(\$ in millions)				Revenue growth				Enterprise value /			
	Market	Enterprise	LTM	2020A-	2021E	LTM gross	LTM EBITDA	Revenue		EBI	TDA ¹
Company	сар	value	revenue	2021E	-2022E	margin	margin	2021E	2022E	2021E	2022E
Commercialization											
Clarivate (CLVT)	\$14,668.8	\$19,076.3	\$1,614.0	45.5%	6.6%	67.2%	33.6%	10.46x	9.80x	23.4x	21.2x
Informa (LSE: INF)	\$11,111.5	\$14,116.1	\$2,079.5	12.2%	24.6%	29.1%	14.8%	5.59x	4.49x	20.8x	13.9x
Model N (MODN)	\$1,186.2	\$1,175.2	\$183.4	21.8%	10.4%	56.1%	(1.1%)	5.83x	5.29x	NMF	41.5x
OptimizeRx Corp. (OPRX)	\$1,298.1	\$1,214.6	\$51.8	40.2%	28.6%	55.6%	7.5%	20.00x	15.56x	NMF	NMF
PaySign (PAYS)	\$136.5	\$134.0	\$20.0	25.3%	36.7%	31.3%	(44.6%)	4.44x	3.25x	NMF	19.3x
Phreesia (PHR)	\$3,087.6	\$2,660.4	\$179.6	33.3%	21.9%	62.8%	(20.1%)	13.42x	11.01x	NMF	NMF
Veeva Systems (VEEV)	\$43,742.5	\$41,537.7	\$1,663.4	25.2%	18.9%	72.6%	28.9%	22.64x	19.05x	NMF	47.2x
Wolters Kluwer (ENXTAM: WKL)	\$27,570.6	\$30,393.5	\$5,359.7	1.9%	3.9%	71.0%	30.1%	5.55x	5.34x	17.8×	16.8x
Average	\$12,850.2	\$13,788.5	\$1,393.9	25.7%	18.9%	55.7%	6.1%	10.99x	9.22x	20.7x	26.7x
Median	\$7,099.6	\$8,388.3	\$898.7	25.2%	20.4%	59.5%	11.2%	8.15x	7.57x	20.8x	20.3x
eClinical											
Cambridge Cog. (AIM: COG)	\$65.2	\$61.1	\$9.3	50.1%	6.9%	80.4%	(9.1%)	4.37x	4.08x	NMF	NMF
Centogene (CNTG)	\$227.1	\$214.0	\$264.2	50.3%	(57.8%)	26.8%	(0.4%)	1.19x	2.83x	NMF	NMF
Certara (CERT)	\$5,501.5	\$5,532.2	\$261.8	18.6%	16.7%	57.4%	4.0%	19.35x	16.58x	NMF	45.8x
Cogstate (ASX: CGS)	\$219.1	\$197.6	\$32.7	NA	NA	53.5%	13.8%	NA	NA	NA	NA
Dassault (ENXTPA: DSY)	\$75,456.3	\$77,016.9	\$5,420.6	8.0%	9.8%	83.4%	21.7%	13.55x	12.33x	36.5x	33.8x
Icon (ICLR)	\$20,623.6	\$19,986.5	\$3,191.3	94.4%	43.8%	28.4%	17.5%	3.69x	2.56x	21.7x	14.8x
Iqvia Holdings (IQV)	\$49,915.0	\$60,678.0	\$12,931.0	22.0%	8.2%	33.6%	17.2%	4.44x	4.10x	20.5x	18.6x
Ixico (AIM: IXI)	\$53.8	\$44.9	\$13.7	NA	NA	67.1%	13.3%	NA	NA	NA	NA
LifeSci Acquisition II (LSAQ)	\$99.7	\$99.3	-	-	-	-	-	-	-	_	-
PPD (PPD)	\$16,402.9	\$19,966.6	\$5,551.9	23.3%	7.0%	66.3%	16.6%	3.53x	3.30x	19.1x	17.3×
Research Solutions (RSSS)	\$67.3	\$56.0	\$31.4	NA	1.3%	32.0%	(0.6%)	1.73x	1.71x	NMF	NMF
Schrödinger (SDGR)	\$4,439.5	\$3,834.9	\$120.7	21.3%	52.9%	51.7%	(68.6%)	28.12x	18.39x	NMF	NMF
Simulations Plus (SLP)	\$902.8	\$784.4	\$46.2	6.7%	14.2%	77.3%	35.9%	17.17×	15.04x	NMF	42.4x
Syneos Health (SYNH)	\$9,758.5	\$12,673.5	\$4,730.4	18.6%	8.7%	23.8%	13.4%	2.42x	2.22x	16.7x	14.9x
Average	\$13,123.7	\$14,367.6	\$2,508.1	31.3%	10.2%	52.4%	5.7%	9.05x	7.56x	22.9x	26.8x
Median	\$2,671.2	\$2,309.7	\$261.8	21.6%	8.7%	53.5%	13.4%	4.37x	4.08x	20.5x	18.6x

Source: Capital IQ.

Notes: * Public comparable company data shown above is as of Sept. 28, 2021. (1) EBITDA multiples less than 0 and greater than 50 labeled "NMF".

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