

# ARTIFICIAL INTELLIGENCE IN HEALTHCARE:

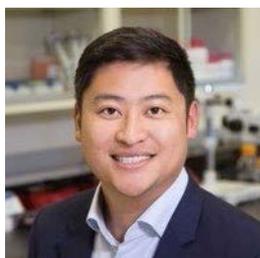
## Algorithms Are Built on Data, Healthcare Is Built on Trust



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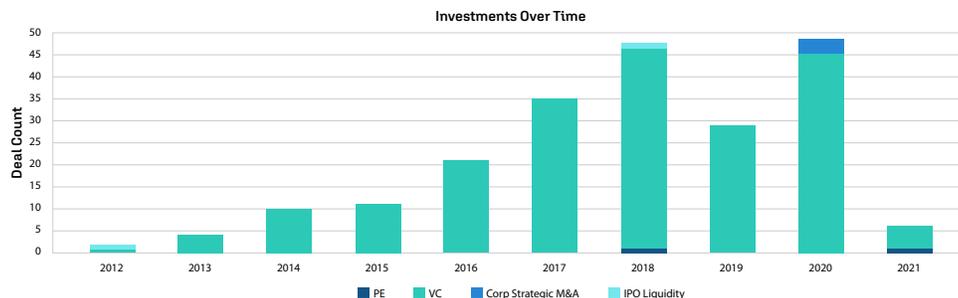
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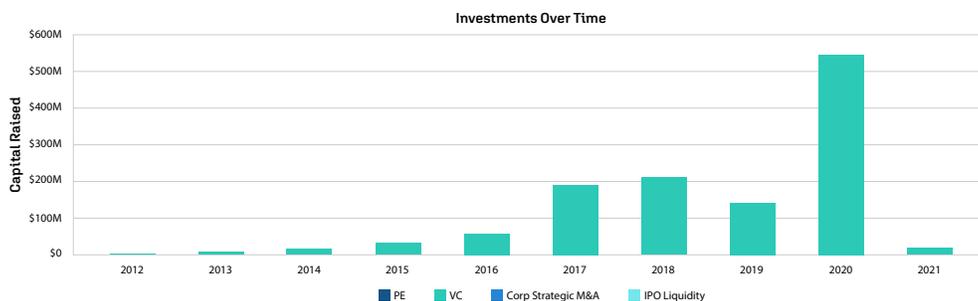
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As data and algorithms begin to impact our healthcare model in meaningful ways, we must recognize that data in healthcare is a means to an end, not the solution.

Industry leaders identified diagnostic imaging early on as a key beachhead market for machine learning applications in healthcare. Pitchbook data shows investments accelerated in 2015 and peaked in 2018, with deals and total amount invested falling by about 30% in 2019. Anecdotally, valuations of artificial intelligence (AI) and diagnostic imaging companies also fell: a low barrier to entry meant more companies competed for fewer investment dollars and differentiated product market fit became increasingly difficult to establish. In 2020, the COVID-19 pandemic reignited founder and investor interest in automating medical imaging analysis, as researchers and clinicians looked for scalable diagnostic tools to manage the pandemic.



Source: PitchBook Data



Source: PitchBook Data

**Figure 1: Investment trends in machine learning for healthcare applications**

Today, there are between 29 and 64 machine learning FDA-approved medical devices and algorithms, depending on definition and technical rigor. At the most rigorous definitions, 21 of 29 (72%) are in the field of radiology, followed by 4 of 29 (14%) with applications in cardiology. Of the 29 approved devices, most of the FDA approvals came in 2018 (13 of 29, or 45%), with fewer approved in 2019 (10 of 29, nearly 35%).



“UNDERSTANDING THE PATIENT JOURNEY AND NUANCED INSIGHTS INTO HOW DECISIONS ARE MADE IS MORE RELEVANT IN THE AGE OF TECHNOLOGY, NOT LESS.”

Armed with the benefit of hindsight as we approach three years post the 2018 investment boom, we look at business model evolution, technical metrics, lessons learned, and remaining challenges for machine learning applications in medical imaging.

### Usability of Machine Learning Applications

Interest in applying machine learning to medical imaging grew out of technical overlaps with other industries that have successfully leveraged imaging data, found productmarket fit, and developed highly scalable solutions, such as agriculture and autonomous vehicles. There is also a well-understood need for medical imaging due to a limited supply of trained clinicians with core knowledge and well-documented variability in diagnostic outcomes due to the complexity of images and variety of parameters.

To date, machine learning techniques have overcome technical, regulatory, and early adoption challenges of diagnostic imaging and have yielded promising real-world results, but they have also highlighted new challenges. As the industry moves beyond proof of concepts, products must be able to generate market traction, demonstrate scalability, and impact patient experience or outcome. Once machine learning-based products have shown a track record of safety, efficacy, and market adoption, the industry will need to transition from “supervised” algorithms to “unsupervised” (or “deep learning”) to drive the next stage of growth. In order to achieve this, clinicians must trust and appreciate the technology; the market data today suggest they do not.

### When Machine Meets Healthcare

Studies now clearly demonstrate that AI-based diagnostics can identify areas of interest with equal or better specificity than trained clinicians (Oren O., 2020). However, the heart of data, algorithms, and machine learning is probabilities, and human beings tend not to make personal decisions according to probabilities. Healthcare decisions are driven by clinicians and patients, not by statistics. This disconnect between data and human decision-making is an enormous barrier to technology adoption. Indeed, market research by Veranex (formerly Ximedica) and others (e.g., McKinsey) has highlighted usability challenges from both the practitioner and patient point of view and reveals a distrust between engineering data, clinicians, and patients. Understanding the patient journey and nuanced insights into how decisions are made is more relevant in the age of technology, not less.

As technology becomes more prevalent in healthcare, developers of algorithmic solutions must lean into the humanity of healthcare and recognize the significant mental and financial burden of technology disruption in healthcare. Market adoption is only possible when solutions move beyond technical metrics and prioritize the stakeholders, considering the user journey, human factors, and workflow integration.

One example of reducing cognitive burden is addressing the “black box”



reputation of most algorithms, where an application generates an output whose reasoning is not obvious to the clinician, leading to mistrust and low adoption. Because healthcare and diagnostic decision-making can be subtly influenced by myriad internal and external factors, we believe that the way that data and results are delivered is as important as what the conclusions are.

**Figure 2 shows a typical radiology report that could be generated by either a technician or an AI application. While rich in data and technically accurate, the report offers few contextual cues or support to guide the patient or the clinician through a complex conversation.**

# Report

01/01/2021A

## Patient Information

Patient ID:	ABCDE -0001
Name:	John Doe
Age:	70.0 years old at latest exam
Birth Date:	09/03/1940
Sex:	M
Study Date:	12/01/2021

Adding and subtracting volumetric results can show small differences due to rounding.

## Brain Volumetry (ID: ABCDE -0001)

CSF	Brain	ICV
353 cm <sup>3</sup> 20.6% of ICV	1362 cm <sup>3</sup> 79.4% of ICV 72.2nd percentile	1715 cm <sup>3</sup>

## Hippocampus & Lobes Volumetry (ID: ABCDE -0001)

Structure	Total	Percentile
Hippocampus	6.06 cm <sup>3</sup> 0.4% of ICV	22.7
Frontal Lobe	422 cm <sup>3</sup> 24.6% of ICV	90.5
Occipital Lobe	114 cm <sup>3</sup> 6.6% of ICV	12.2
Parietal Lobe	265 cm <sup>3</sup> 15.4% of ICV	35.0
Temporal Lobe	226 cm <sup>3</sup> 13.2% of ICV	43.0
Cerebellum	152 cm <sup>3</sup> 8.8% of ICV	—

Structure	Left	Percentile	Right	Percentile
Hippocampus	2.98 cm <sup>3</sup> 0.2% of ICV	26.0	3.08 cm <sup>3</sup> 0.2% of ICV	21.7
Frontal Lobe	210 cm <sup>3</sup> 12.2% of ICV	87.5	213 cm <sup>3</sup> 12.4% of ICV	91.7
Occipital Lobe	57 cm <sup>3</sup> 3.3% of ICV	11.5	57 cm <sup>3</sup> 3.3% of ICV	17.6
Parietal Lobe	131 cm <sup>3</sup> 7.7% of ICV	27.4	134 cm <sup>3</sup> 7.8% of ICV	44.5
Temporal Lobe	110 cm <sup>3</sup> 6.4% of ICV	43.0	115 cm <sup>3</sup> 6.7% of ICV	42.6
Cerebellum	75 cm <sup>3</sup> 4.4% of ICV	—	76 cm <sup>3</sup> 4.4% of ICV	—

## White Matter Hyperintensities (ID: ABCDE -0001)

	Total	Count
WMH	13.41 cm <sup>3</sup> 1.0% of brain	27 WMH

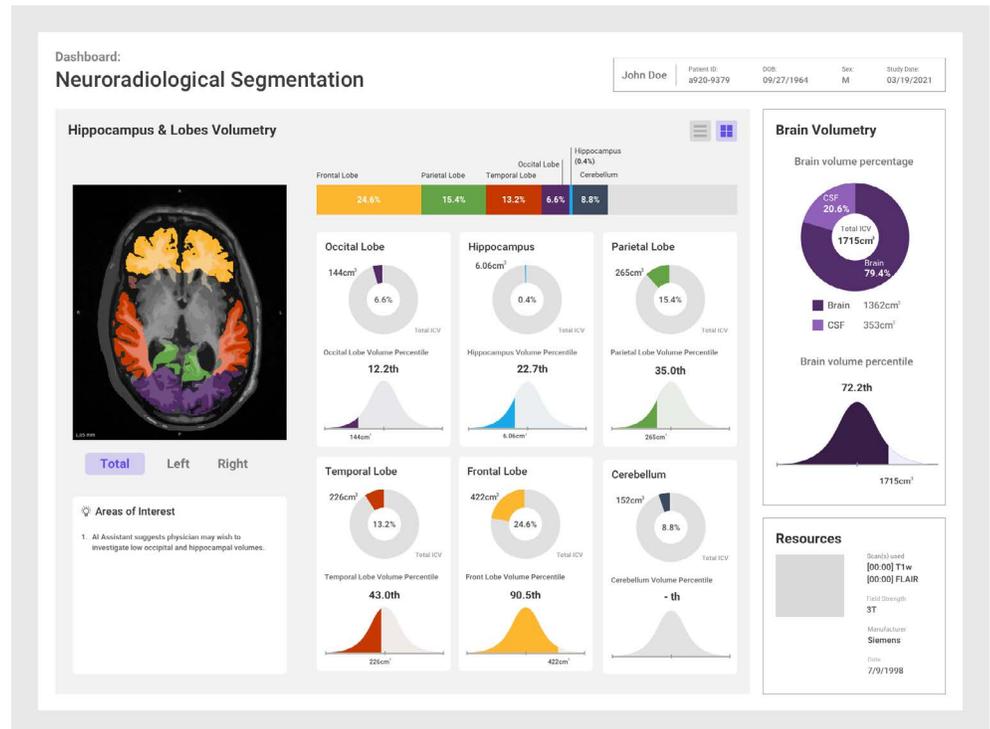
## Resources (ID: ABCDE -0001)

	Scan(s) used	Manufacturer	Field Strength
7/9/1998	[00:00] T1w [00:00] FLAIR	Siemens	3T

Figure 2: Sample radiology report, typical of what is generated today



Conversely, **Figure 3** shows the same data generated by an AI algorithm that incorporates multiple tools that empower the patient to have a meaningful conversation with their physician or when seeking a second opinion.



**Figure 3: Example of an AI-generated radiology report with greater usability (designed by Veranex)**

Note: All design decisions were made to increase usability, clarity, and perception of control. Because the design was not informed by interviews with neuroradiologists, the design does not accurately reflect a clinically relevant prioritization of information, but it demonstrates how design can enhance the usability of AI-generated reports.

- A.** Multiple viewing options (adjustable for user preference) increase the perception of flexibility and customization in an otherwise automated process.
- B.** Clear visual association between real anatomy and calculated outcomes improves encoding depth and increases speed of understanding.
- C.** Modern, cognitively considerate data visualization improves comprehensibility of the report. The design also includes the ability to select individual structures and explore data specific to that structure to confirm, deny, or provide fodder for AI and clinician hypotheses.
- D.** Spatial and visual differentiations between data with which you can interact and data serving as static information improves workflow and allows users to drill down for deeper investigations of important elements without sacrificing space at the top level.
- E.** Toggling between total volumes and hemispheric volumes allows access to more specific data at a single point of use.
- F.** No conclusions are made on the clinician's behalf; instead potential areas of interest or irregular results are indicated to help clinicians prioritize their investigations. This allows users to incorporate context into their clinical decision-making and increases the clinician's perception of the AI as a potentially trustworthy partner, rather than a digital dictator.
- G.** Explicit traceability to patient scans and other raw data provides some level of transparency to an inherently opaque process. By removing as much of the "black box" as we can, we strengthen the foundation upon which users' trust can be built.



## Conclusion

As technology continues to play a greater role in our healthcare decisions, the emerging and legacy healthtech industry will strive to deliver the best experience, drive positive outcomes, and generate growth by leaning into the patient and user, building meaningful relationships between patients and stakeholders (Birkhauer J., 2017), and deeply understanding the human condition. If the product is to succeed, all designs, including information and communication, must account for cognitive capabilities, limitations, and patterns.

As algorithms play an ever-greater role in healthcare, the need to design for the human experience is more important than ever. Data should enhance the patient-clinician relationship, not replace it.

Veranex has spent the last three decades designing and developing products to enhance the human experience. With the increasing implementation of artificial intelligence and data analytics, medical devices must adapt their designs to ensure that these new technologies remain approachable, usable, and effective. Designing with these goals in mind increases adoption rates, reduces training needs, creates trusting relationships, and drives economic value for our clients.

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Veranex is the only truly comprehensive, global, tech-enabled service provider dedicated to the medical technology industry. Offering expert guidance from concept through to commercialization and across the development continuum, Veranex enables accelerated speed to market, controlled development costs, development risk mitigation, and accelerated market viability assessment.

At every stage, Veranex customers realize efficiencies in cost and time, while our integrated and comprehensive solutions unify the entire development process. With Veranex as your end-to-end partner, you're well-positioned to deliver the safest, most effective devices to improve outcomes to patients everywhere.



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