AI in Medicine: From Concept to Clinic

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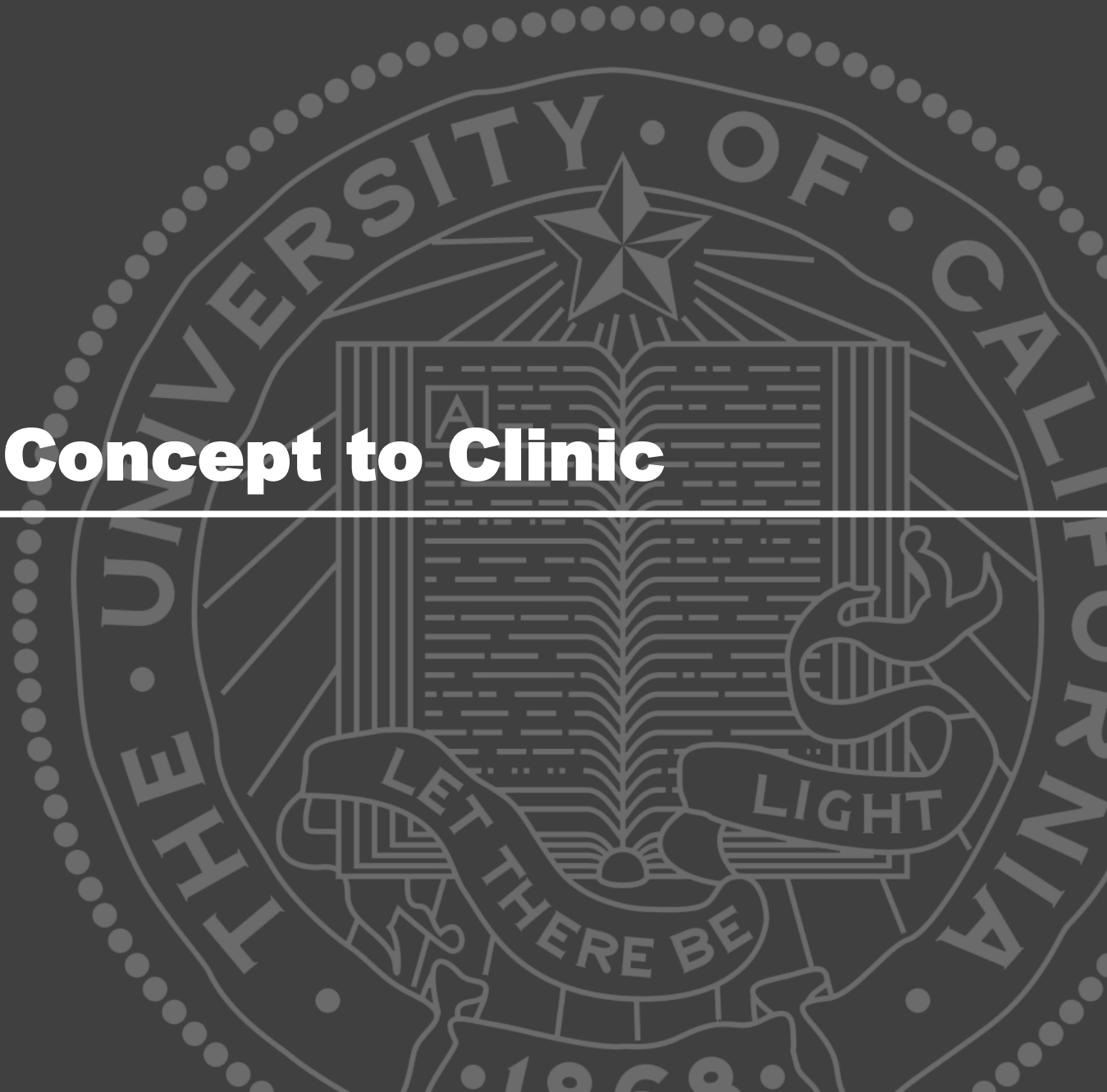
University of California Irvine

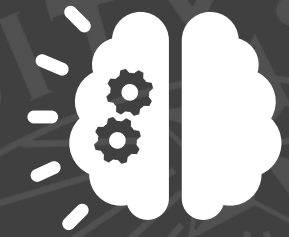


Disclosures

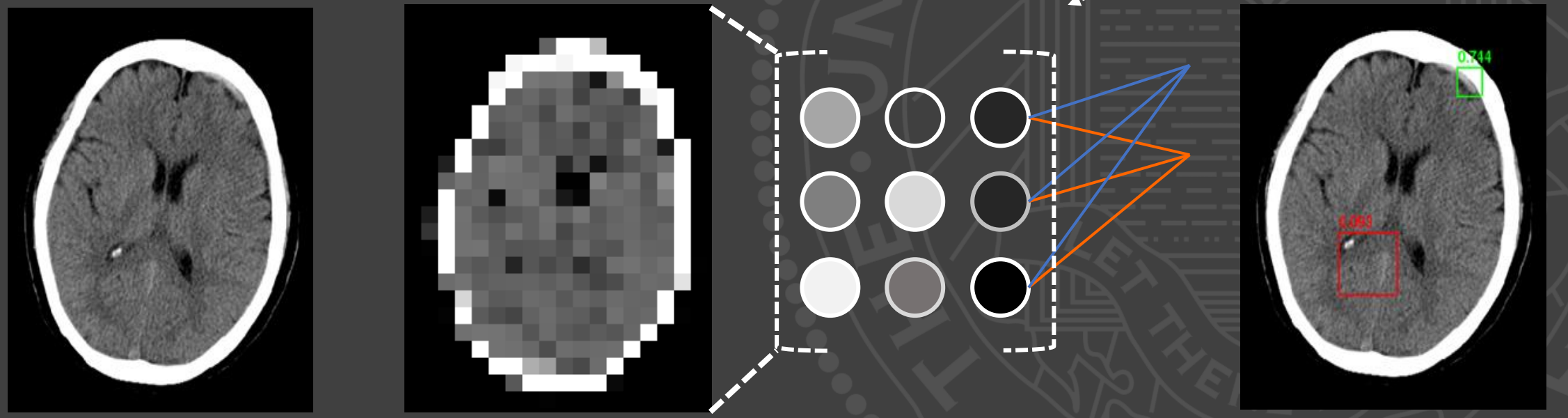
Cofounder	Avicenna.ai
Consultant	Bayer Medical; Olea Medical; Canon Medical
Other	Novocure (grant)
	NVidia Corporation (GPU partnership)
	Amazon Web Services (cloud compute)

Deep Learning

Virtual brain (network of neurons)

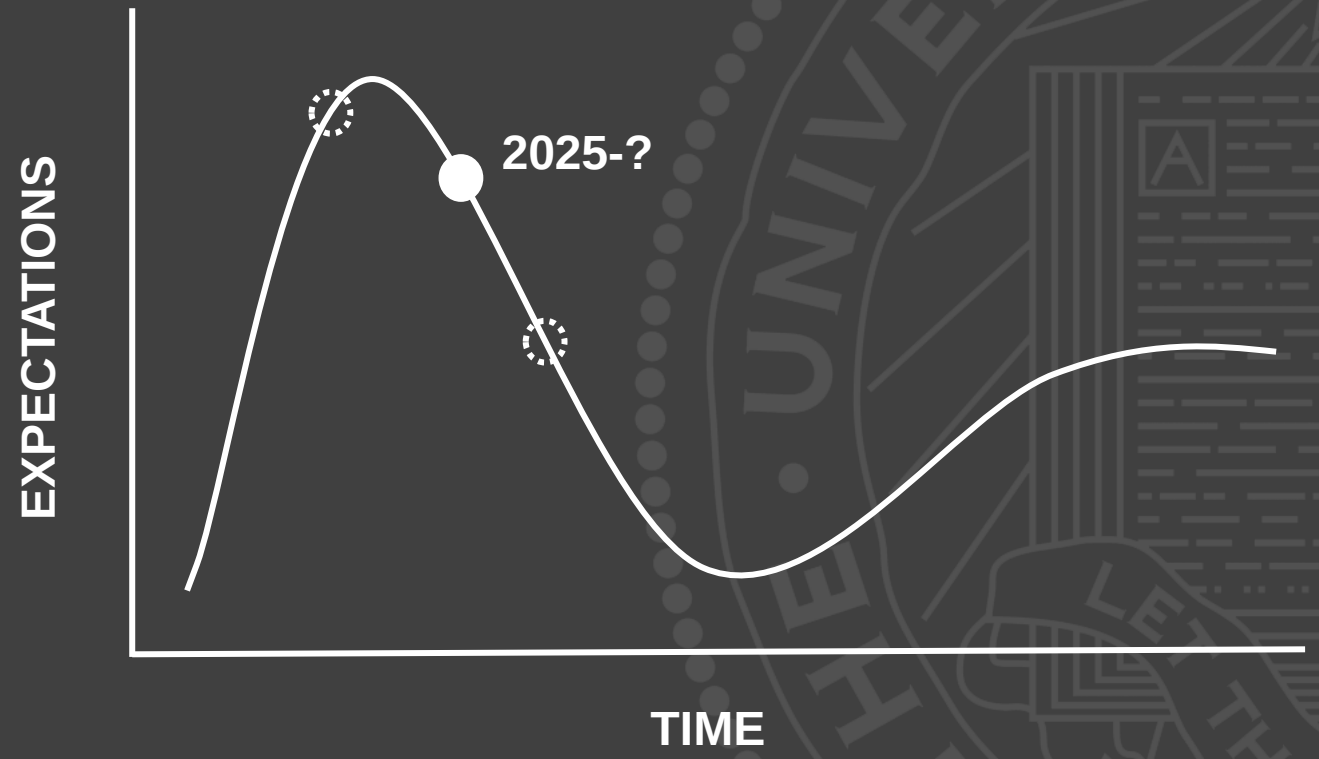


No explicit representation of knowledge to be learned



Trends

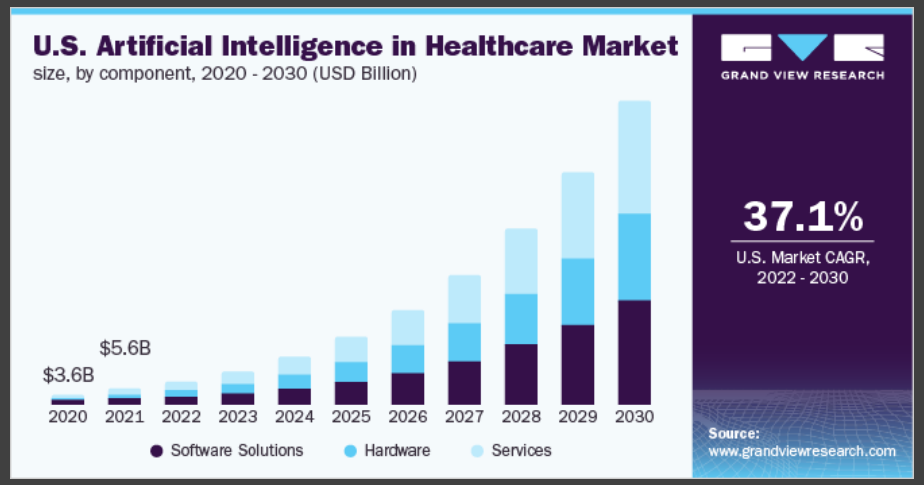
What is the **current** state of **AI** in radiology?



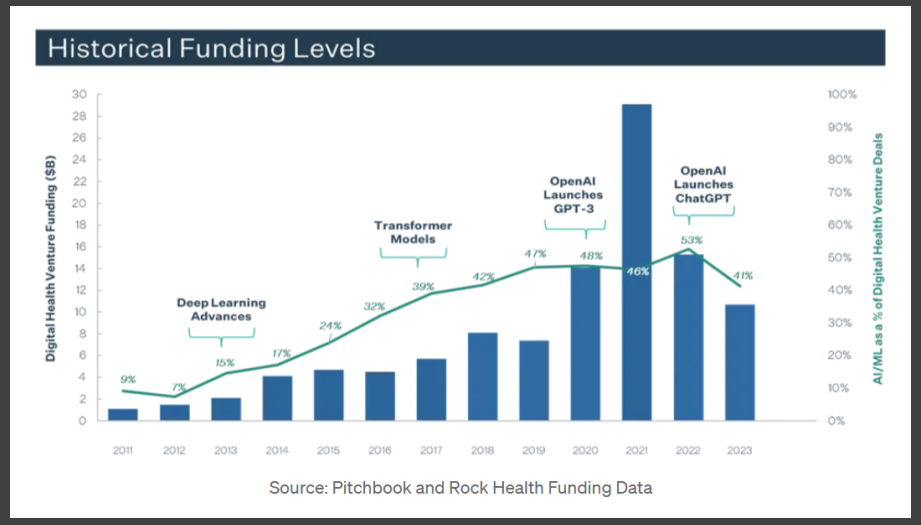
Adapted from **Gartner Hype Cycle**

Trends: Business

AI In Healthcare Market Report, 2022-2030



Flare Capital Partners, 2024



FDA approvals

100+ algorithms

- 2019: 51
- 2020: 99
- 2021: 109
- 2022: 138
- 2023: 177
- 2024: 125

Top Categories

1. Image Processing
2. Triage
3. CAD and Oncology

https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices

Quantification

Segmentation Applications

Examples

- Cardiac MR
- Oncology
- Traumatic brain injury
- Dementia
- Neurovascular

Popular because…

- Technology: solvable (**-ed**)
- Data: **less data** requirements
- Regulatory: not considered diagnostic

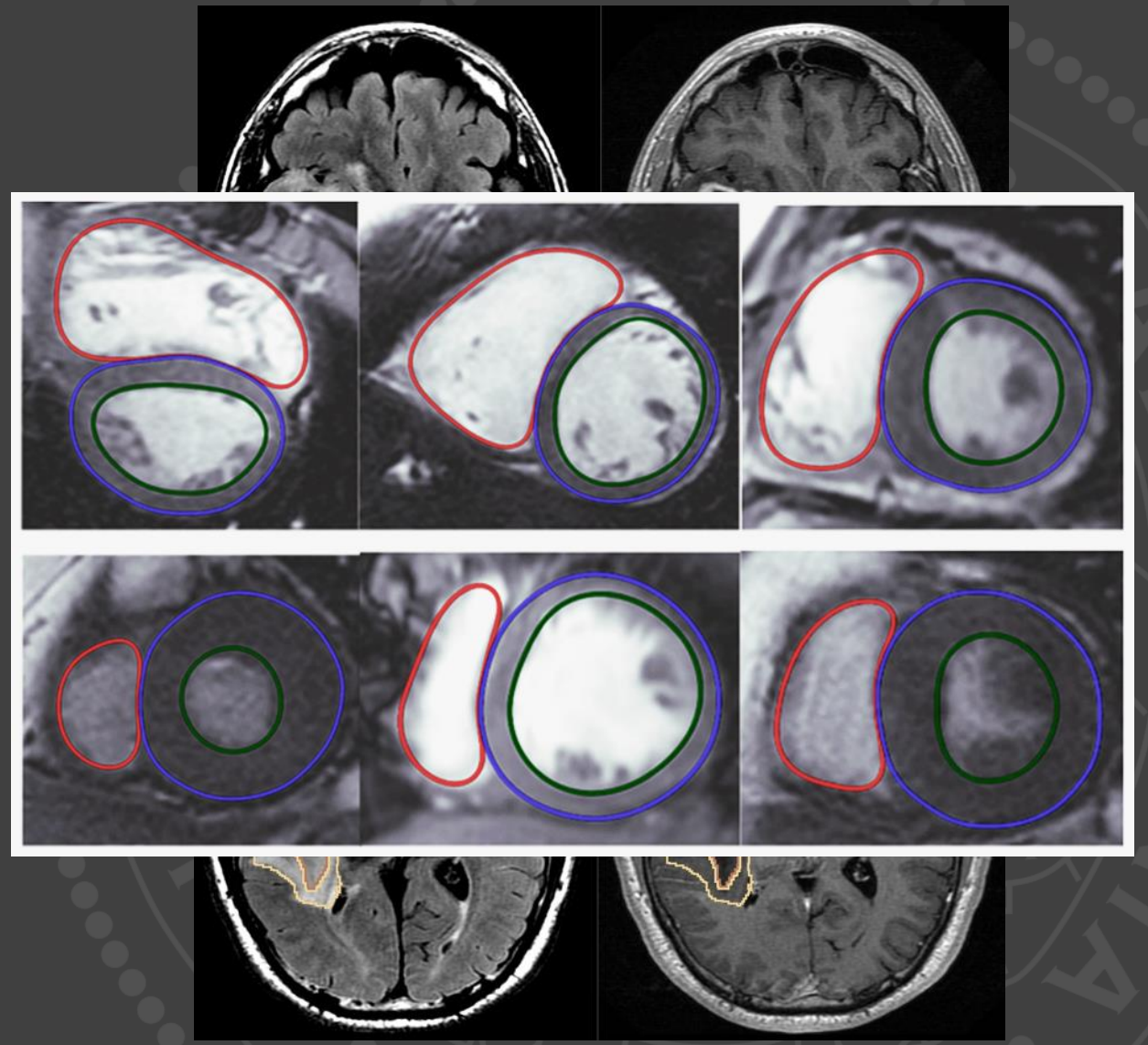


Image Reconstruction

Deep learning reconstruction

Examples

- MR reconstruction (*k*-space)
- CT reconstruction (sinogram)
- Super-resolution
- Artifact removal

Popular because…

- Technology: generative models
- Data: data may be **simulated**
- Regulatory: not considered diagnostic

Image Reconstruction

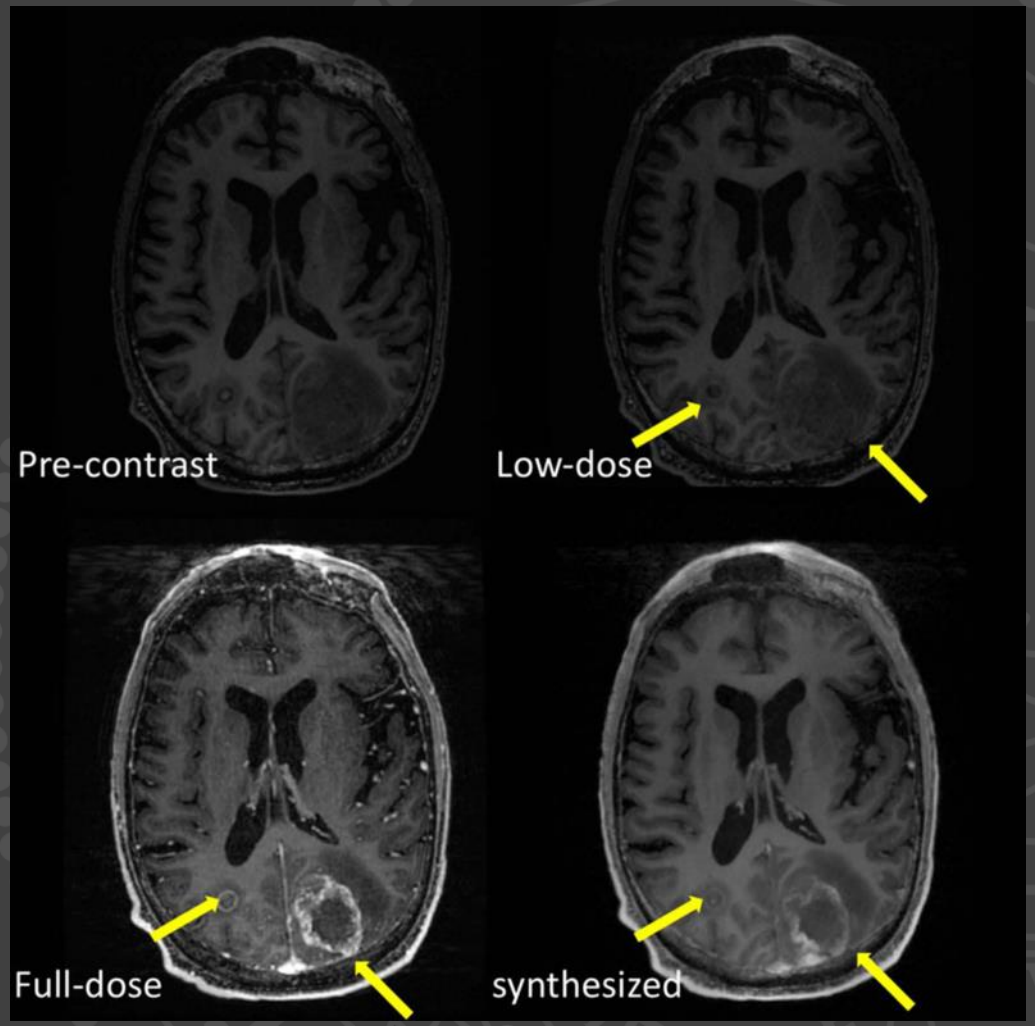
Opportunities

Low-dose reconstruction

- Low contrast dose
- Low radiation dose
- Low radiotracer dose

Popular because…

- Technology: difference learning
- Data: data may be **simulated**
- Regulatory: not considered diagnostic



Gong, Enhao, et al. "Deep learning enables reduced gadolinium dose for contrast-enhanced brain MRI." JMRI 48.2 (2018): 330-340.

Triage

Triage Applications

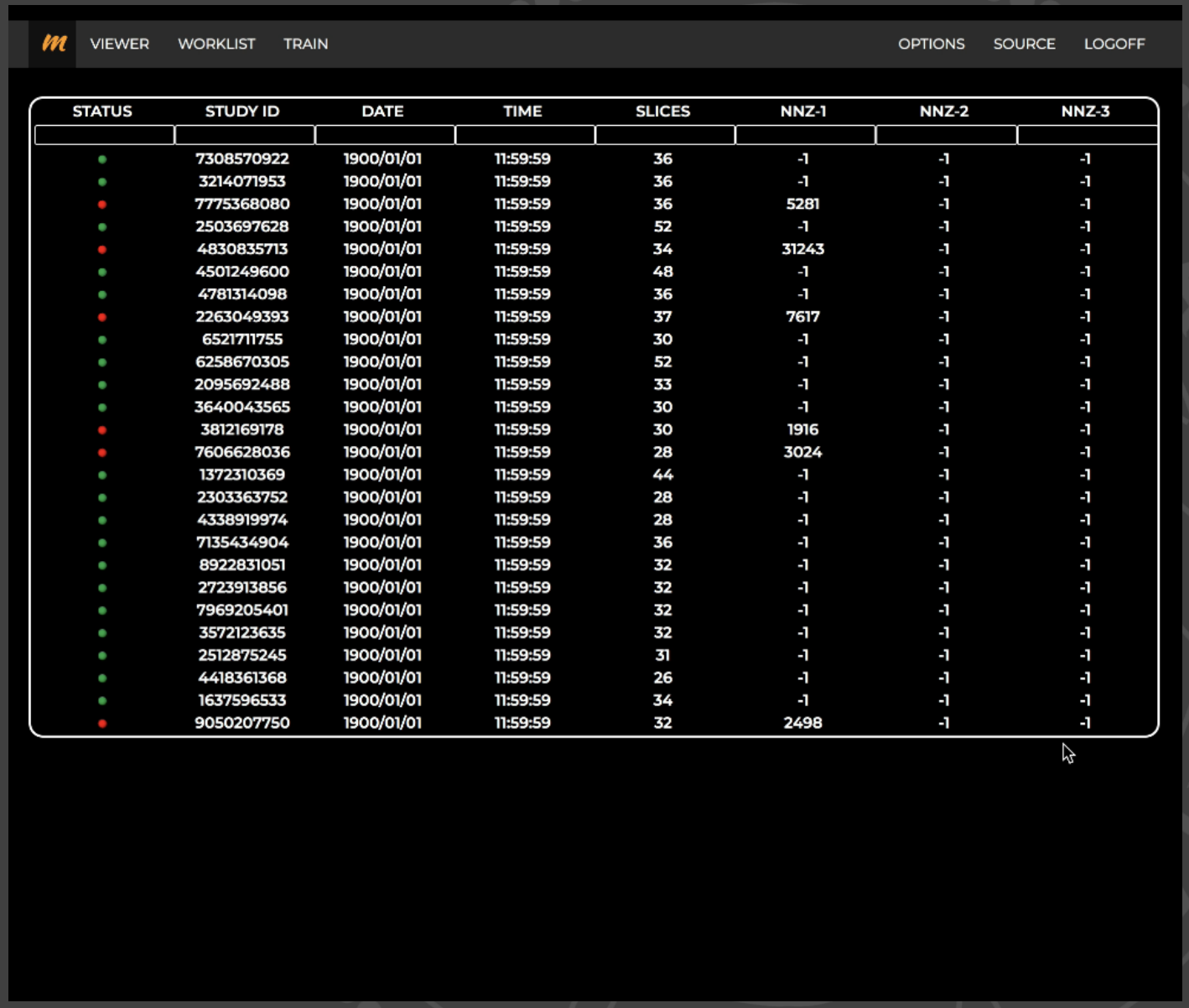
Examples

- Hemorrhage
- Large vessel occlusion
- Stroke / ASPECTS
- Cervical spine fracture
- Pulmonary embolus
- Chest radiographs

Popular because…

- Technology: solvable (**-ed**)
- Data: **common** disease processes
- Regulatory: **FDA triage** pathway[1]

[1]Relatively simple clearance



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	7775368080	1900/01/01	11:59:59	36	5281	-1	-1
	2503697628	1900/01/01	11:59:59	52	-1	-1	-1
	4830835713	1900/01/01	11:59:59	34	31243	-1	-1
	4501249600	1900/01/01	11:59:59	48	-1	-1	-1
	4781314098	1900/01/01	11:59:59	36	-1	-1	-1
	2263049393	1900/01/01	11:59:59	37	7617	-1	-1
	6521711755	1900/01/01	11:59:59	30	-1	-1	-1
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	1637596533	1900/01/01	11:59:59	34	-1	-1	-1
	9050207750	1900/01/01	11:59:59	32	2498	-1	-1

Stroke Triage

Hemorrhage Detection (NCCT)

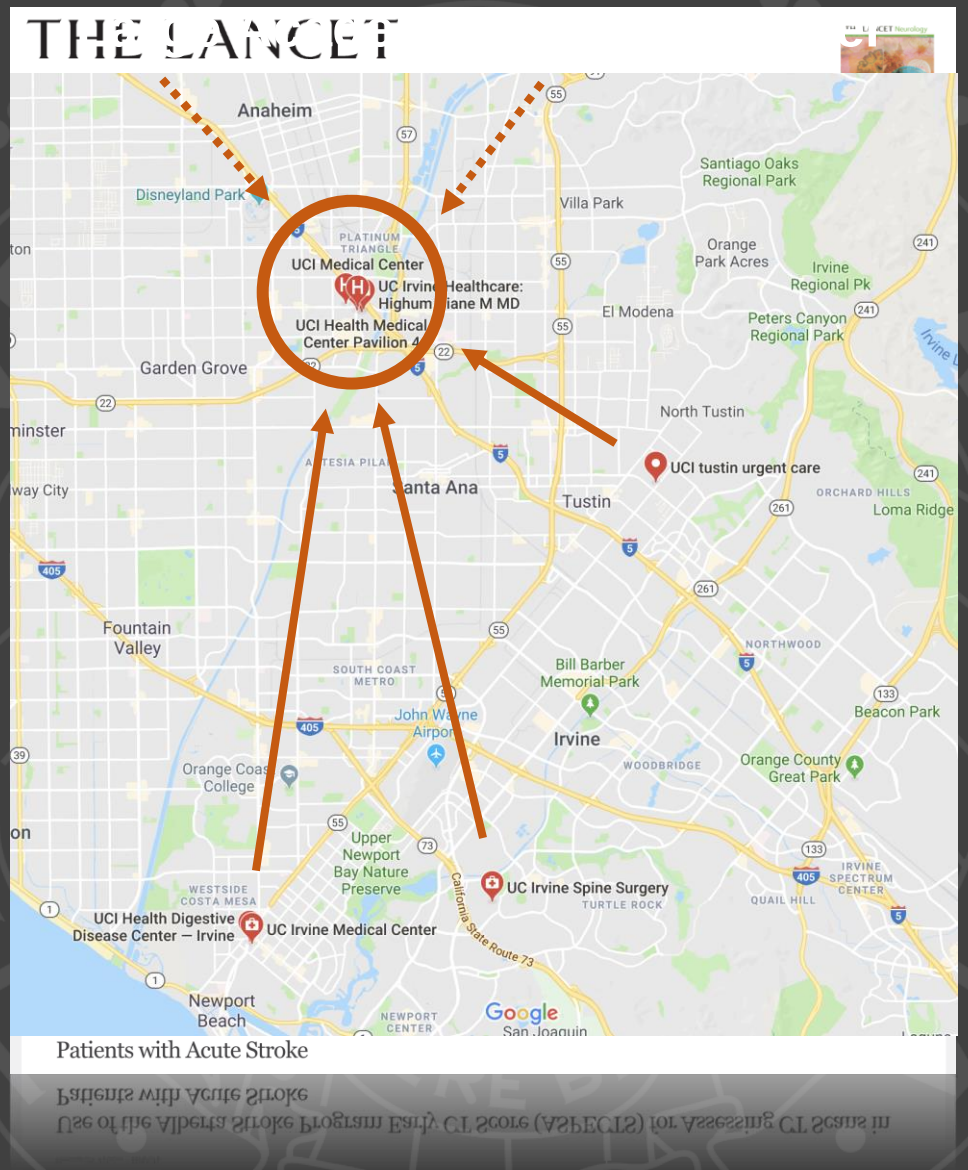
↓

Vessel Occlusion (CTA)

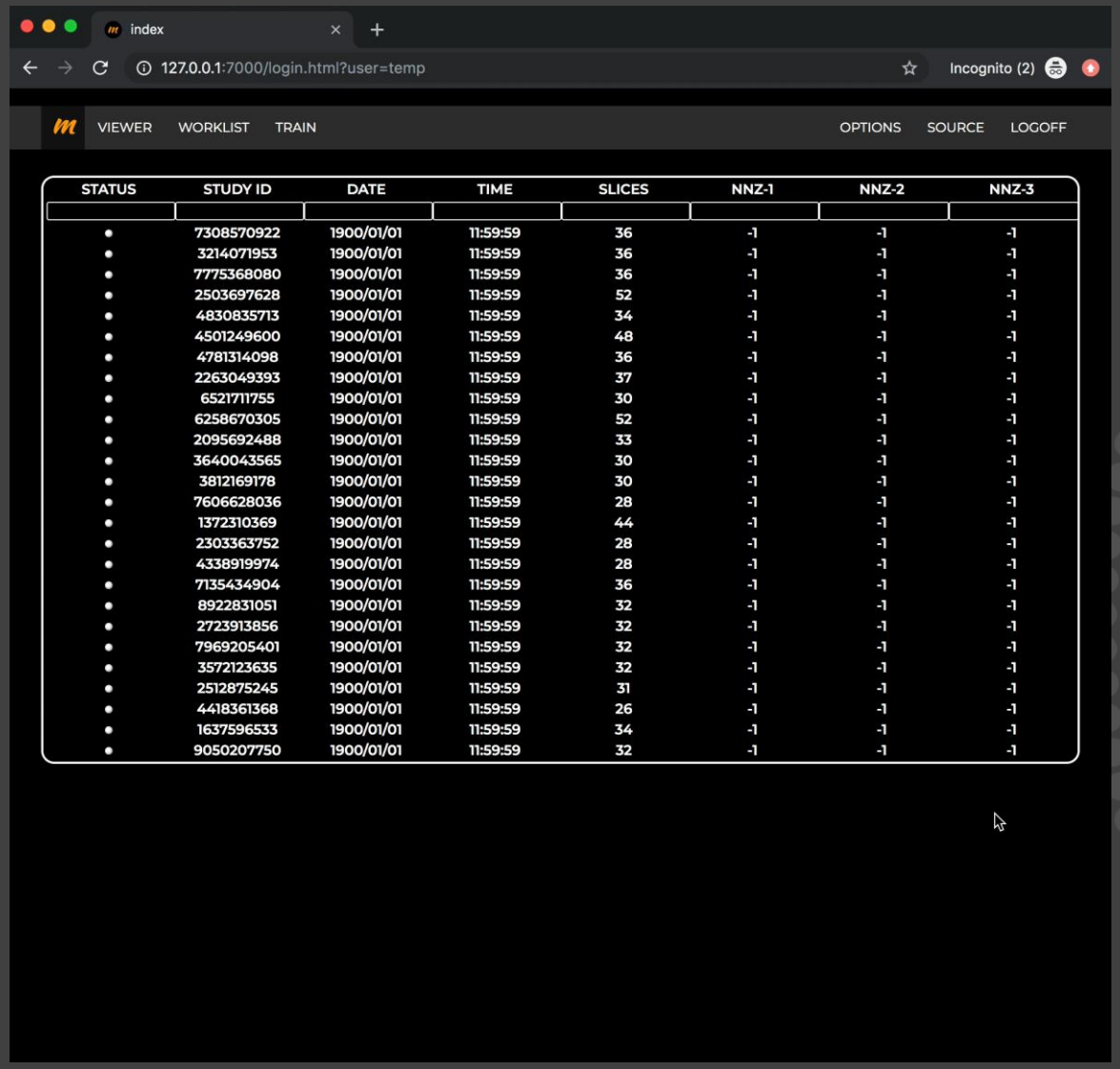
↓

Ischemic Core

ASPECTS score
Perfusion



Hemorrhage (CT)



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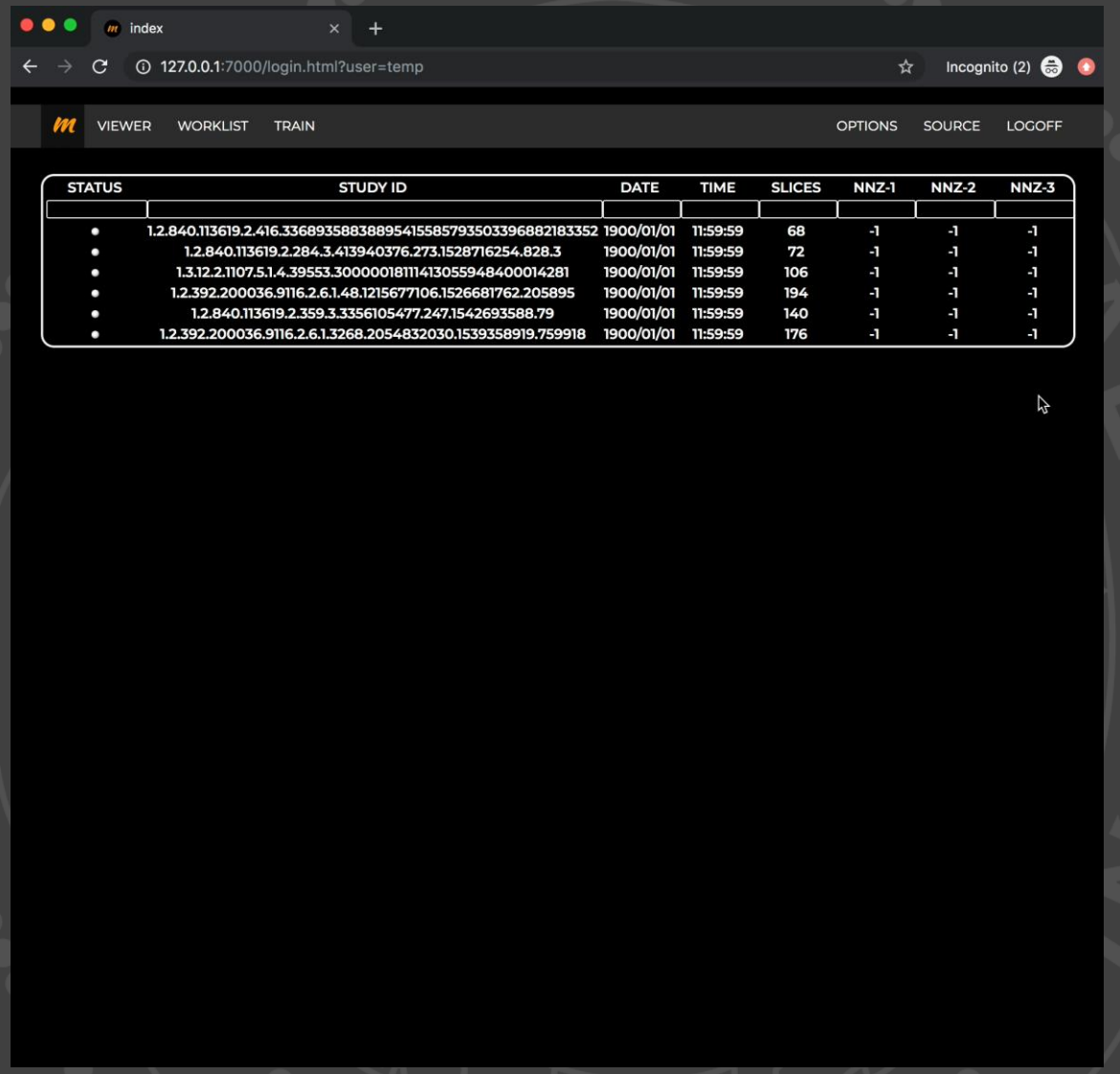
•	4418361368	1900/01/01	11:59:59	26	-1	-1	-1
•	1637596533	1900/01/01	11:59:59	34	-1	-1	-1
•	9050207750	1900/01/01	11:59:59	32	-1	-1	-1

Occlusion (CTA)



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•	1.2.392.200036.9116.2.6.1.48.1215677106.1526681762.205895	1900/01/01	11:59:59	194	-1	-1	-1
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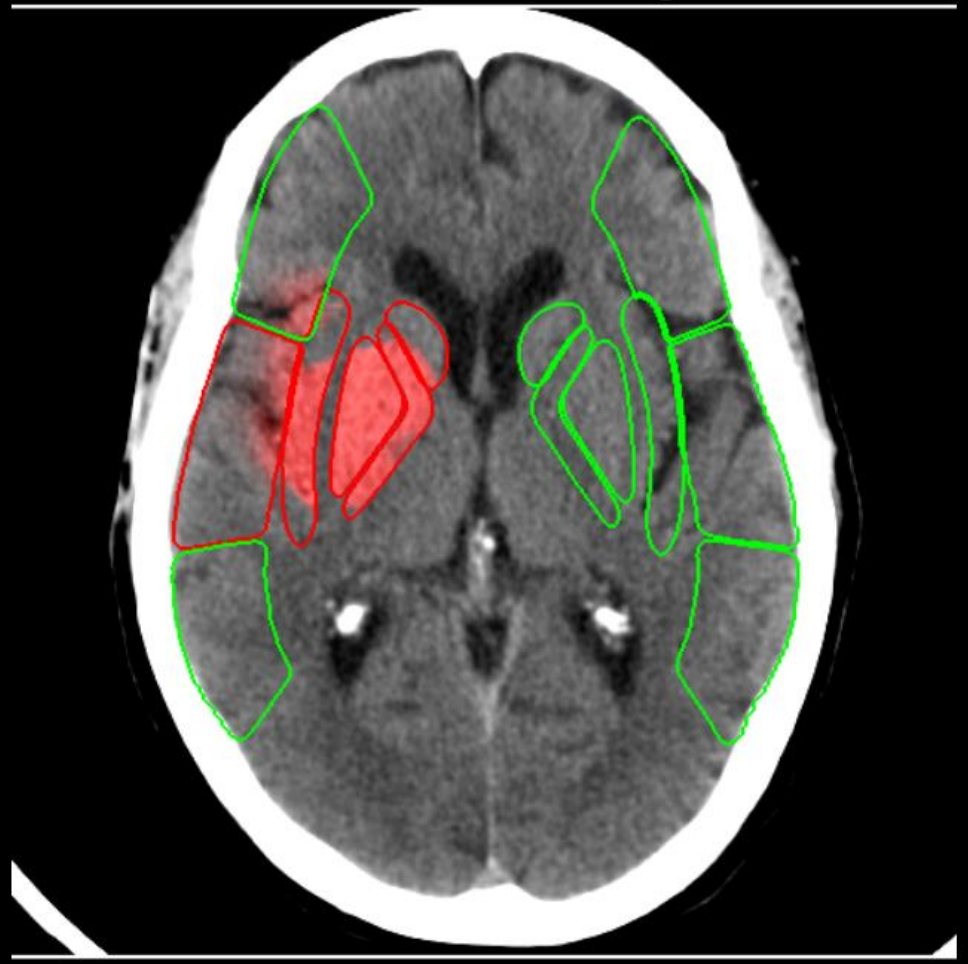
•	1.2.392.200036.9116.2.6.1.3268.2054832030.1539358919.759918	1900/01/01	11:59:59	176	-1	-1	-1

Stroke Triage: ASPECTS



Areas of suspected low attenuation and/or sulcal effacement are shown in transparent red overlay

Anatomic ASPECTS regions identified as normal are outlined in green

Anatomic ASPECTS regions identified as infarct are outlined in red:

Right Internal Capsule, Caudate, Lentiform, Insula, M2, M6

Automatically generated

ASPECT Score

4/10

Hounsfield Units Mean

Right	Left
C 31.3	C 32.4
IC 28.4	IC 29.0
I 30.3	I 29.4
L 29.5	L 33.0
M1 32.9	M1 33.1
M2 30.9	M2 31.7
M3 33.2	M3 33.9
M4 29.5	M4 31.6
M5 29.7	M5 31.1
M6 30.4	M6 31.7
4 / 10	10 / 10

Stroke Triage

REVIEW ARTICLE

Artificial Intelligence and Acute Stroke Imaging

J.E. Soun, D.S. Chow, M. Nagamine, R.S. Takhtawala, C.G. Filippi, W. Yu, and P.D. Chang

Table 3: Commercially available software platforms and their applications[a]

Software	Applications	Machine Learning Algorithm	Imaging Technique
Aidoc	ICH: identifies ICH, triage, and notification	DL	CT
	LVO: identifies LVO, triage, and notification	DL	CTA
	CTP: orchestration of third-party perfusion results	Other	CTP
Avicenna.AI	CINA ICH: identifies ICH, triage, and notification	DL	CT
	CINA LVO: identifies LVO, triage, and notification	DL	CTA
	CINA ASPECTS: ASPECTS scoring; provides heat map	DL	CT
Brainomix	e-Blood: identifies and quantifies ICH volume with mask overlay	DL	CT
	e-ASPECTS: identifies ASPECTS, voxelwise map of early ischemic change, and core infarct volume	Predominantly ML	CT
	e-CTA: identifies and notifies LVO, collateral score, and collateral vessel attenuation; voxelwise map of collateral deficit	Combination of DL and traditional ML	CTA
	e-ASPECTS HDVS: identifies and measures hyperattenuated vessel	DL	CT
	e-Mismatch: identifies mismatch on CTP and MR imaging	Deconvolution	CTP, MR imaging, MRP
RapidAI	Rapid ICH: identifies and classifies ICH	DL	CT
	Rapid ASPECTS: identifies ASPECTS, measurement, and scoring	RF	CT
	Rapid CTA: identifies and notifies LVO and collateral vessel attenuation	Other	CTA
	Rapid CTP: identifies mismatch on CTP, collateral maps, and scoring	Other	CTP
	Rapid MR: identifies mismatch on MR, collateral maps, and scoring	Other	MR imaging, MRP
Viz.ai	Viz ICH: identifies and triages ICH	DL	CT
	Viz LVO: identifies and triages LVO	DL	CTA
	Viz CTP: automated perfusion color maps and calculations	DL	CTP

Note:—HDVS indicates hyperattenuated vessel sign.

[a] Some, but not all, of these products have FDA, European, and/or worldwide regulatory clearance at the time of publication.

Stroke Triage

Improved **outcomes**

- 20-70 min reduction in door-to-puncture time
- Improved 5-Day NIHSS (51%)
- Improved discharge mRS (37%)
- Improved 90-Day mRS (40%)

Whaley M, et al. Use of Artificial Intelligence Shows Significant Reduction in Door to Skin Puncture Times at a Stroke Center. Sky Ridge Regional Medical Center. 2020.

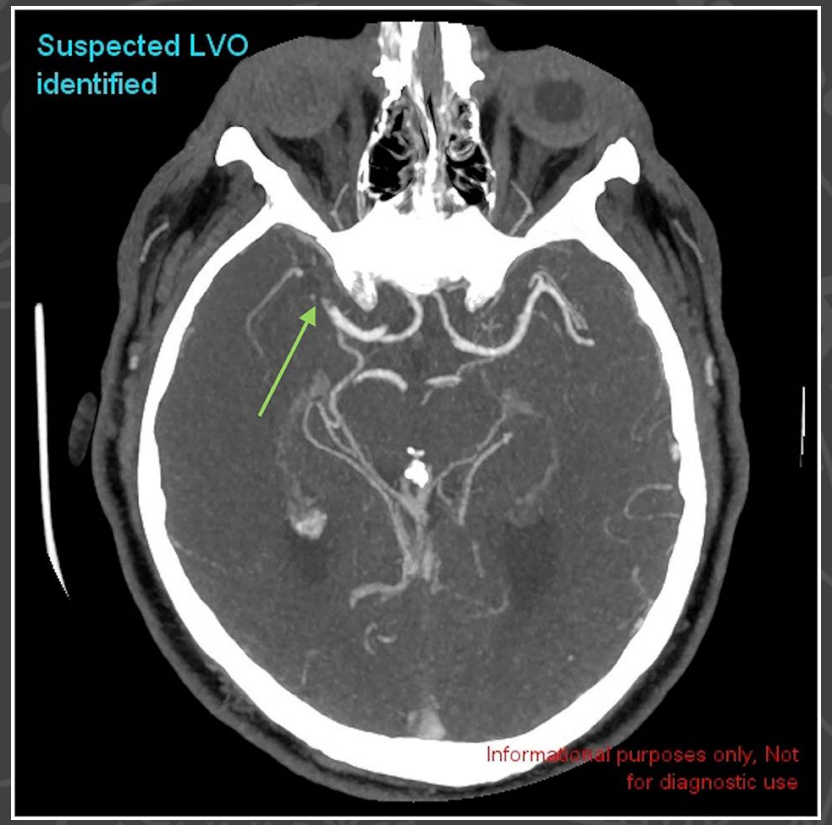
Hassan, A et al. Early Experience Utilizing Artificial Intelligence Shows Significant Reduction in Transfer Times and Length of Stay in a Hub and Spoke Model (n. 43). International Stroke Conference 2020.

Estimated **$11M** savings / year

- 6-20% of LVOs missed
- 50% reduction in missed LVOs

van Leeuwen, Kicky G., et al. "Cost-effectiveness of artificial intelligence aided vessel occlusion detection in acute stroke: an early health technology assessment." *Insights into imaging* 12.1 (2021): 1-9.

Fasen, B. A. C. M., et al. "CT angiography in evaluating large-vessel occlusion in acute anterior circulation ischemic stroke: factors associated with diagnostic error in clinical practice." *American Journal of Neuroradiology* 41.4 (2020): 607-611.



Built a model. **Now what…?**

Multisite Validation

Is your model generalizable?

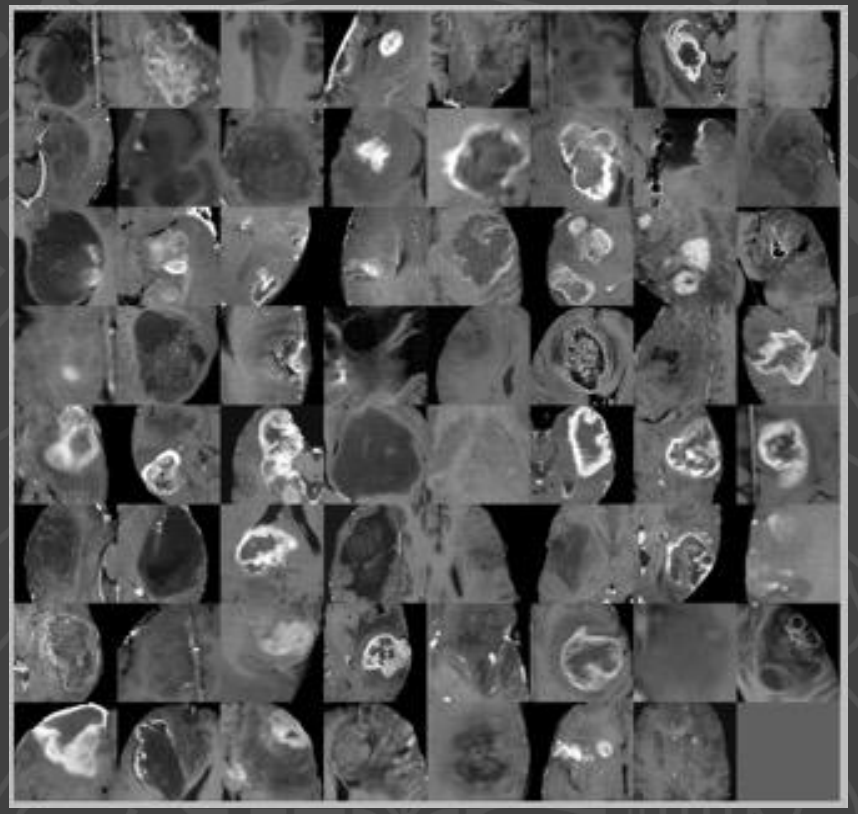
May need additional fine-tuning.

UCI Datasets

- **100,000** CT exams (~18 months consecutive)
- **6,000** mammograms + breast MRIs (breast cancer)
- **2,000** brain MRIs (glioma, MS, dementia)
- **1,000** chest CTs (pneumonia)
- **500** head CTAs (stroke)
- **400+** prostate MRIs
- **400+** abdomen CTs (renal protocol)

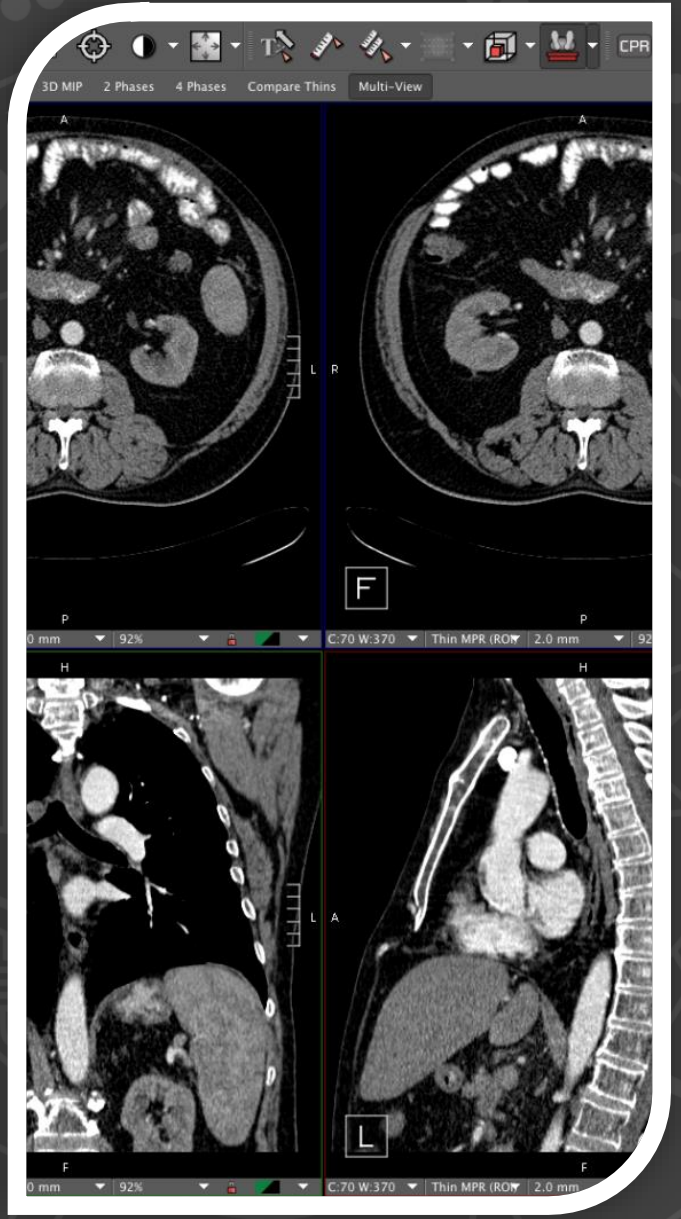
External Datasets

- MICCAI Grand Challenges
- Cancer Imaging Archives (~**50,000** exams)
- RSNA / SIIM / Kaggle
- ASNR / ASFNR Challenge Datasets



THE CANCER IMAGING ARCHIVE

Trends: Deployment



When do I need **FDA clearance?**

Investigation Device

When do you need **FDA clearance**?

- Required when “your device is **marketed** or **commercially distributed**”
- You do not need FDA approval to develop, evaluate, or test a device

When do you need an **investigational device exemption** (IDE)?

- Local IRB review alone is most often sufficient
- If IRB determines a device poses “significant risk”, an IDE must also be approved by FDA

Baseline requirements for either:

- Informed consent from all patients
- Labeling stating that the device is for investigational use only

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https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/investigational-device-exemption-ide
https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-notification-510k

FDA Classes

FDA Device Classes

Class I: General Controls
Class II: General Controls + Special Controls
Class III: General Controls + Premarket Approval

Most Software-as-a-Medical Device (**SaMD**) is consider **FDA Class II**.

Important:

Class I/II ⟶ **510k** (or De Novo)
Class III ⟶ PMA

Product Classification

FDA Home ▸ Medical Devices ▸ Databases

1 to 15 of 15 results
software Radiology

Results per page 25

New Search — Export to Excel — Help

Product Code	Device		Regulation Number	Device Class
PZO	Software For Visualization Of Vascular Anatomy And ...	Medical Image Management And Processing ...	892.2050	2
QQE	Image Management Software For Planning Of Otologic ...	Medical Image Management And Processing ...	892.2050	2
POK	Computer-Assisted Diagnostic Software For Lesions ...	Radiological Computer-Assisted Diagnosti...	892.2060	2
QAS	Radiological Computer-Assisted Triage And Notifica ...	Radiological Computer Aided Triage And N...	892.2080	2
QBS	Radiological Computer Assisted Detection/Diagnosis Software For Fracture		892.2090	2
QDQ	Radiological Computer Assisted Detection/Diagnosis Software For Lesions Suspicious For Cancer		892.2090	2
QFM	Radiological Computer-Assisted Prioritization Soft ...	Radiological Computer Aided Triage And N...	892.2080	2
QHA	X-Ray Angiographic Imaging Based Coronary Vascular ...	Angiographic X-Ray System	892.1600	2
QIH	Automated Radiological Image Processing Software	Medical Image Management And Processing ...	892.2050	2
QKB	Radiological Image Processing Software For Radiati ...	Medical Image Management And Processing ...	892.2050	2
QTZ	Radiological Image Processing Software For Ablatio ...	Medical Image Management And Processing ...	892.2050	2
QVD	Radiological Machine Learning Based Quantitative Imaging Software With Change Control Plan		892.2055	2
QWO	Radiology Software For Referral Of Findings Related To Fibrotic Lung Disease.		892.2085	2
QZL	Post-Ablation Tissue Response Prediction Software		892.2052	2
SAO	Radiology Software For Opportunistic Evaluation Of Low Bone Mineral Density		892.1171	2

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm

FDA 510(k)

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm

510(k) Premarket Notification

FDA Home › Medical Devices › Databases

A 510(K) is a premarket submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent, to a legally marketed device (section 513(i)(1)(A) FD&C Act) that is not subject to premarket approval.

Learn more...

Search Database

Help Download Files

510K Number | Type | Product Code

Center | Combination Products

Applicant Name | Cleared/Approved In Vitro Products

Device Name | Redacted FOIA 510(k)

Panel | Third Party Reviewed

Decision

Decision Date to | Clinical Trials

Sort by: Decision Date (descending)

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New Search | Back To Search Results

Device Classification Name	radiological computer-assisted triage and notification software
510(k) Number	K233968
Device Name	CINA-iPE
Applicant	Avicenna.AI ZI Athelia, 297 Av. Du Mistral Bat. A La Ciotat, FR 13600
Applicant Contact	Stephane Berger
Correspondent	Hogan Lovells US LLP 555 13th St. NW Washington, DC 20005

U.S. FOOD & DRUG ADMINISTRATION

The data was provided from multiple U.S. and OUS clinical sites, with 56.4% (215) cases coming from U.S. clinical sources. The independence of the standalone validation dataset from the training data was ensured using data from independent sites and different time periods. There were 181 (47.5%) positive iPE (images with PE) cases and 200 (52.5%) negative iPE cases included in the analyses. The data was acquired primarily by 4 different scanner makers (GE-31.5%, Philips-28.3%, Siemens-26%, and Canon-13.9%) and 39 different scanner models.

Device Sensitivity [95% CI] and Specificity [95% CI] were computed against the groundtruth established by consensus of three US-board-certified expert radiologists.

As a primary endpoint, the global Sensitivity and Specificity were found to be 87.8% [95%CI: 82.2% - 92.2%] and 92.0% [95%CI: 87.3% - 95.4%], respectively. These findings achieved the 80% performance goal of the study and are similar to the results reported for the predicate BriefCase device (Aidoc Medical) which demonstrated Sensitivity and Specificity of 89.7% [95%CI: 80.8% - 95.5%] and 90.1% [95%CI: 81.5% - 95.6%], respectively.

Additionally, subgroup analysis was reported in terms of sensitivity [95%CI] for each lesion location (main, interlobar, lobar and segmental) as presented in the following Table:

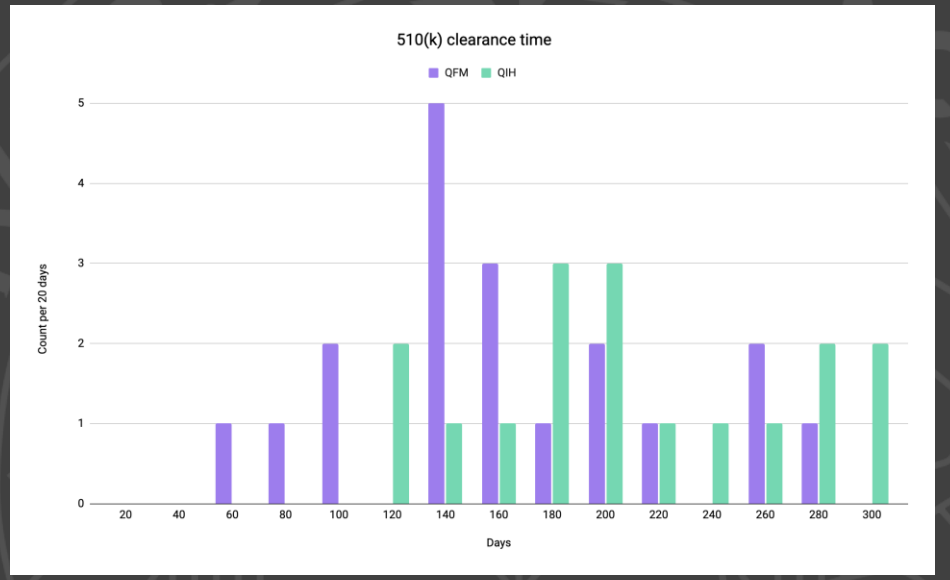
Table 1: Stratified statistical analysis (Sensitivity [95%CI]) regarding arterial segments.

Arterial Segment	Sensitivity [95% CI]
Main (N = 55)	96.3% [87.5% - 99.6%]
Interlobar (N = 73)	94.5% [86.6% - 98.5%]
Lobar (N = 127)	92.9% [87.0% - 96.7%]
Segmental (N = 179)	88.3% [82.6% - 92.6%]

FDA Timeline

Day 0	**Online submission (eSTAR)** • Pay MDUFA fee ($5-20k)
Day 15	**Acceptance review** • Minimum criteria for review
Day 60	**Substantiative Review** • Interactive Review • Addition Information Review
Day 90	**Decision Letter** • Substantially Equivalent • Not Substantially Equivalent

- Pre-submission (60-75 days prior)
- Consulting company: $25-40k



Average between **154 to 201 total days** to receive a 510(k) decision for SaMD products, if you are deemed substantially equivalent to a predicate device by the FDA.

Regulatory

FDA 510(k) categories

Computer-aided triage (nearly **all** deep learning startups currently) → [**no** image annotation]

CADe (detection)

CADx (diagnosis)

Business Plan

Useful software tool ≠ **Financially** viable application

How much would you be willing to **pay**?

Considerations

- Increased speed (limited)
- Decreased errors (limited)
- Improved patient outcomes
- Increased therapeutic window (**best**)

Reimbursement codes are valuable.

Stroke Triage: CMS NTAP

First approval: large-vessel occlusion

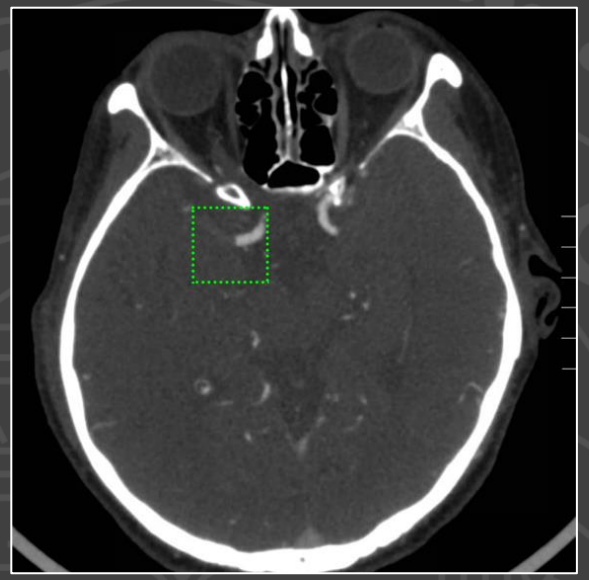
New Technology Add-on Payment (NTAP)

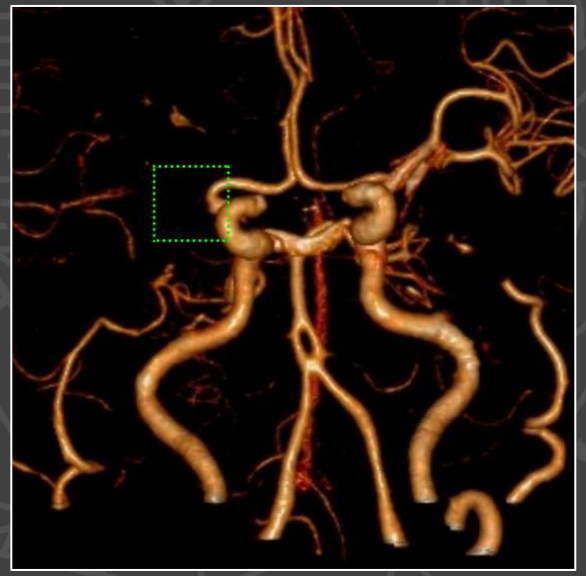
- Announced September 2020
- Predicate device: Viz.ai (but not manufacturer specific)

Requirements

- New technology (up to Sept 2021)
- “Same or similar mechanism of action”
- Inpatient Medicare fee-for-service (FFS) patients
- Up to $1040.00 beyond MS-DRG reimbursement

Key: demonstrated improvement in patient outcomes over baseline standard-of-care





A2IR @ UCI

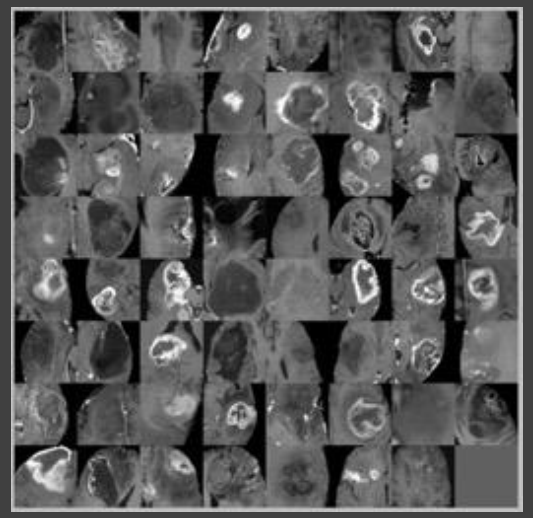
Vision Statement

"A new cross-disciplinary initiative to develop and deploy medical tools based on artificial intelligence technology spanning across the UC Irvine Healthcare system."

Center for Applied AI Research,
UC Irvine Health

A2IR @ UCI

Infrastructure

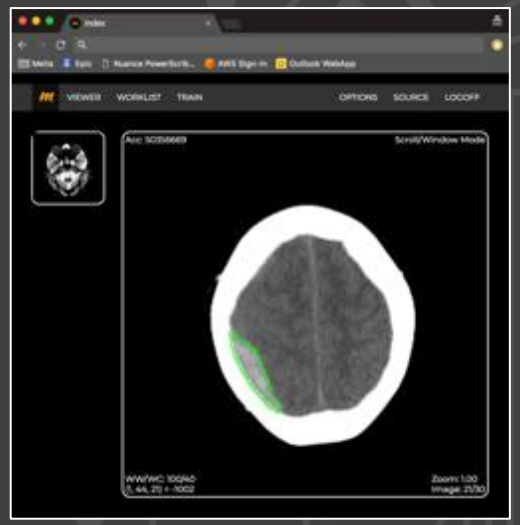


DATA

Full programmatic access to PACS archive, over 3M+ exams (0.3 PB) and reports;
deidentification services

COMPUTE

Largest GPU cluster (1,900+ TFLOPs) in any Radiology Department in US

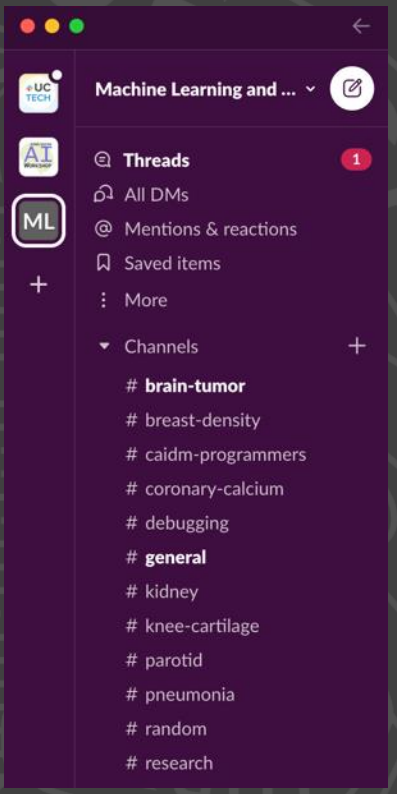


TOOLS

In-house tools for annotation; clinical deployment stack in test and production PACS environments

PROJECTS

Active collaborations between CAIDM data scientist team and clinical radiology faculty



CAIDM *Slack* channel

A2IR @ UCI

Radiology PACS

Existing access already to UCI digital PACS archives

UCI Medical Center

Clinical deployments for software tools across imaging disciplines (radiology, pathology, dermatology, ophthalmology, GI, etc.)

Pathology Data

Existing access already to digital scanners at both UCI hospital and main campus

CAIDM

Deployment Hub

DEPLOY

PHI compliant compute resources

RESEARCH

Primary research compute environment for non-PHI data

UCI Outpatient Centers

Yorba Linda
Newport Imaging
Irvine Outpatient Center

UCI Health Affiliates

Stroke center patient transfers
Oncology referrals
Outpatient surgery referrals

Questions?

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UC Irvine Medical Center
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