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Interventional Radiology &  
Image-Guided Medicine  
Department of Radiology  
and Imaging Sciences



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# Training, Validation and Generalizability Pre-Market Assessment and Validation

Dr. Judy W Gichoya  
Assistant Professor (IR + Informatics) Emory University  
Co-Director @ HITI Lab

 @judywawira



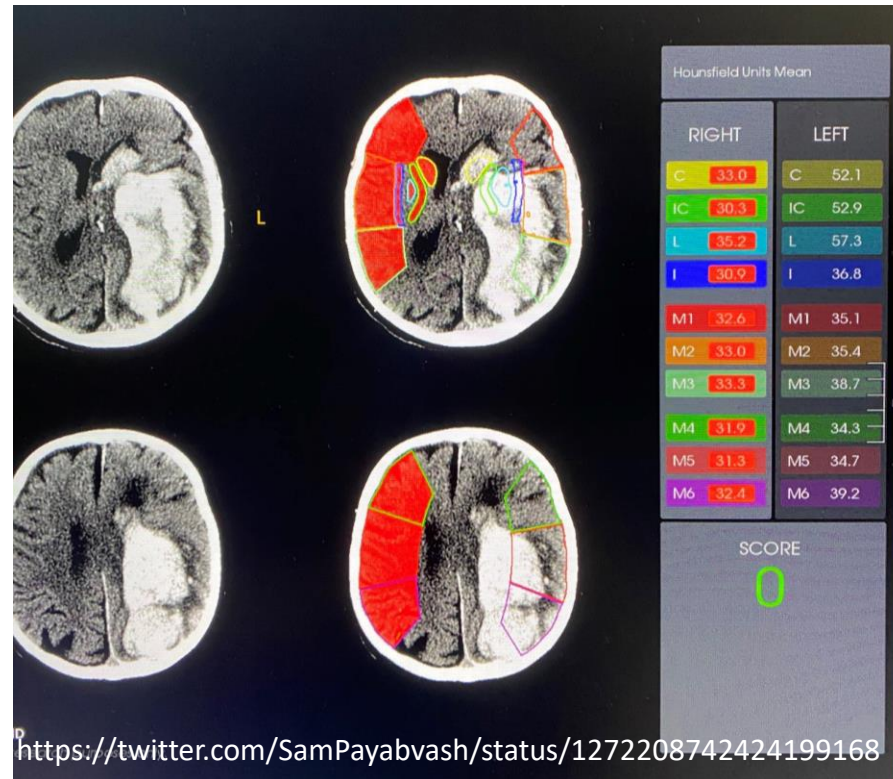
# Disclosures

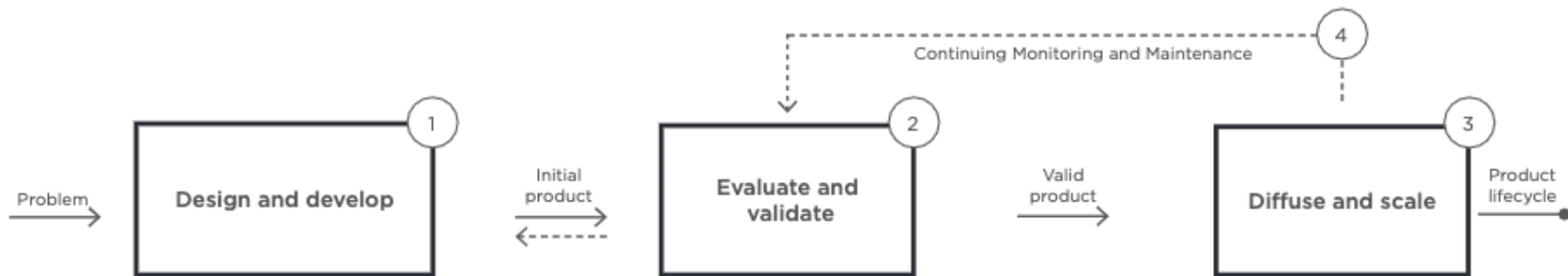
- RSNA Trainee Editorial Board
- RSNA CIRE committee
- ACR AI Advisory council
- ACR Informatics Commission
- SIIM Global outreach committee
- Softbrew LTD – Global health consulting



# Objectives

- Brief Background
- Reality check
- Future





<p><b>Settings and funding</b></p> <ul style="list-style-type: none"> <li>- Industry (generally self-funded or industry partnerships)</li> <li>- Academia (generally university-funded)</li> <li>- True Start-Up (generally self-funded, angel seed investors)</li> <li>- Philanthropy (e.g., Gordon and Betty Moore Foundation)</li> <li>- Government (DOD, DARPA Funding)</li> </ul> <p><b>Data types and sources</b></p> <p>Retrospective or Prospective:</p> <ul style="list-style-type: none"> <li>- Internal (e.g., Group A team with Group A data)</li> <li>- External (e.g., Group A team with Group B data)</li> <li>- Public (e.g., Group A team with Public data)</li> </ul> <p><b>Typical team progression</b></p> <p>Individual idea → Initial collaboration → Interdisciplinary</p> <p><b>Productise existing model</b></p> <p>Existing models can be translated into novel models to rapidly develop new products</p>	<p>2a <i>In silico</i></p> <p><b>Clinical utility</b></p> <ul style="list-style-type: none"> <li>- Demonstration of real-world workflow improvements</li> <li>- Adoption shown to be useful and natural</li> </ul> <p><b>Statistical validity</b></p> <ul style="list-style-type: none"> <li>- New population, same efficacy</li> <li>- Large and diverse initial training set</li> <li>- Robust models</li> </ul> <p><b>Economic utility</b></p> <ul style="list-style-type: none"> <li>- Prospective demonstration</li> <li>- Retrospective demonstration</li> </ul>	<p>2b</p> <p style="writing-mode: vertical-rl; transform: rotate(180deg);">Internal/temporal</p>	<p>2c <b>Care integration</b></p> <p>Clinical integration → <b>Clinical validity</b></p> <p>Technical integration → <b>Statistical validity</b></p> <p>Operational integration → <b>Economic validity</b></p>	<p>2d</p> <p style="writing-mode: vertical-rl; transform: rotate(180deg);">External</p>	<p><b>Deployment modalities</b></p> <ul style="list-style-type: none"> <li>- Fully integrated EHR services e.g., Epic or Cerner plug-ins</li> <li>- Partially integrated EHR services e.g., HBI Solutions, Palo Alto, California, USA</li> <li>- Standalone Models e.g., Kidney Failure Risk Equations, MDCalc</li> </ul> <p><b>Funding (product)</b></p> <ul style="list-style-type: none"> <li>- Self-funding (e.g., eCart)</li> <li>- Partnerships with industry (e.g., Kensci, Seattle, Washington, USA)</li> <li>- Government grants (e.g., NHS with DeepMind/Streams)</li> <li>- Acquisition (e.g., Google acquired Streams)</li> <li>- Health-tech incubators (e.g., MATTER, Chicago, Illinois, USA)</li> </ul> <p><b>Drivers of adoption</b></p> <ul style="list-style-type: none"> <li>- Academic Dissemination</li> <li>- Marketing and sales</li> <li>- Reimbursement and payment models</li> <li>- Strategic differentiation</li> <li>- Incentive programmes</li> </ul>
<p><b>Regulatory</b></p>					

# Background



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- RSNA 2019 – 173 self identified companies
- DSI FDA approved algorithms list – 62 companies
- FDA approval not enough! & != clinical utility
- 6 % - external validation with multi-institutional data or prospective validation
- Pubmed “Radiology” + “AI” vesus “Radiology” + “AI” + “clinical practice”  
OR “clinical trials”
- Clinicaltrials.gov “Radiology+AND+AI” – 66 registered trials, 10 in practice



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# Background



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- 10 records for randomized clinical trials, 2 published
- 81 non randomized trials – 9 prospective , 6 tested in real life setting
- Median experts 2-9
- Limited access to datasets + code
- High risk of bias n= 58
- < 50 % adherence for 12 of 29 TRIPOD items
- N = 31 need for prospective trials



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Nagendran et al - Artificial intelligence versus clinicians: systematic review of design, reporting standards, and claims of deep learning studies

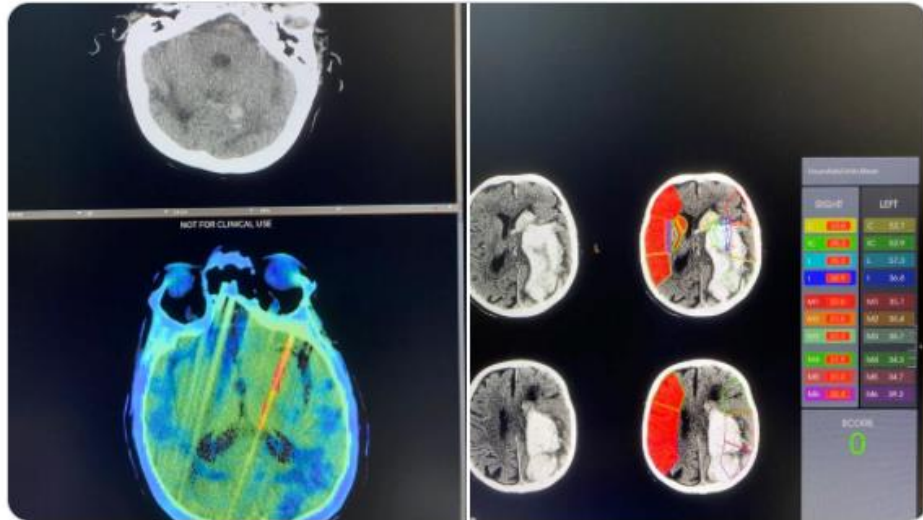
June 2020



Sam.Payabvash  
@SamPayabvash

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While being swamped during weekend call, I had few moments of amusement with epic failures of computer assisted diagnosis! picking up streak artifact for bleed while missing actual hemorrhage; calling ASPECT of 0 in right hemisphere because of large hematoma on the left #AI 🤔🧠



12:46 PM · Jun 14, 2020 · Twitter for iPhone



**RapidAI** @RapidAI · Jun 17

Replying to @SamPayabvash

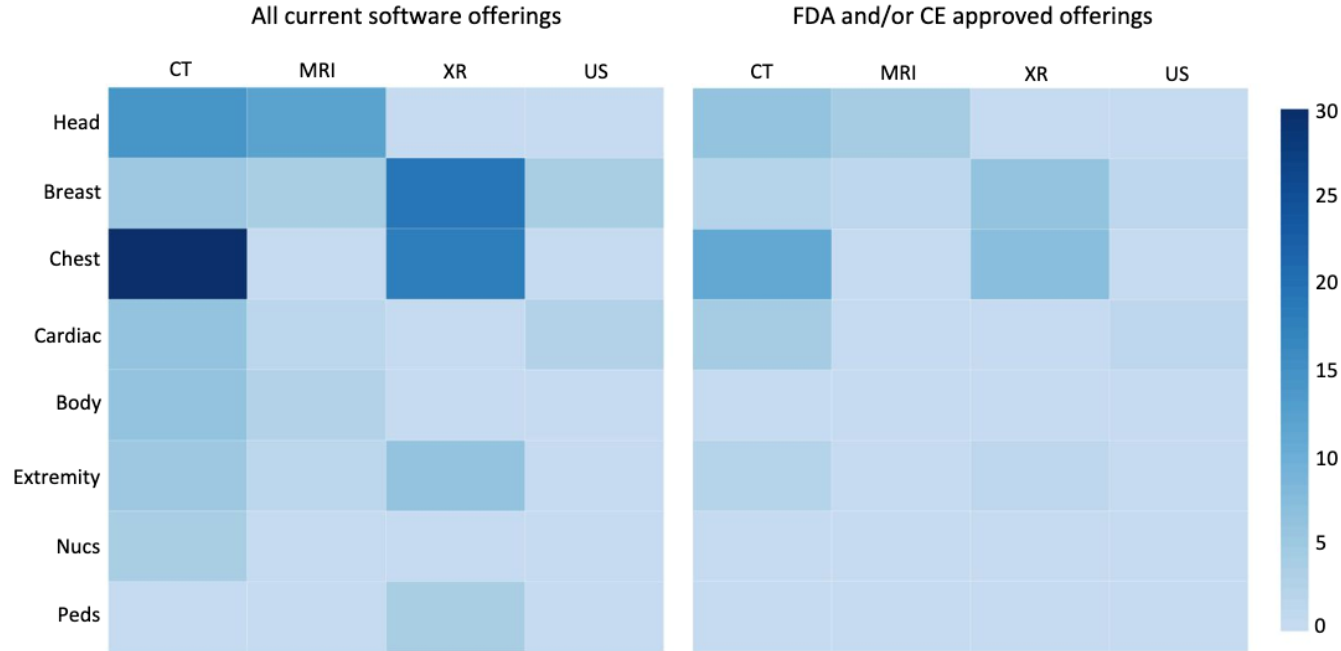
@SamPayabvash the ASPECTS application can give an ASPECTS score in the presence of LVO. It is not designed to find hemorrhages. Our ICH module is FDA cleared to notify physicians of the suspicion of hemorrhages as small as 1ml. You can find more info here:



Intracranial Hemorrhage Detection in Minutes (ICH...  
Rapid ICH uses AI technology to quickly triage non-contrast CT (NCCT) cases and notify clinicians of ...  
[rapidai.com](https://rapidai.com)









# Considerations for purchase

- Motivation for AI purchasing \$\$\$
- Data Ownership and Privacy - local versus cloud
- Cost structures – subscription , capital purchase ?
- Reported model performance – internal testing

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## Customers Who Bought This Item Also Bought

**The State of Radiology AI – Considerations for Purchase  
Decisions and Current Market Offerings**





Subspecialty	Modality	Value Proposition	Validation methodology	Data Source	Performance Metrics	Implementation	Cost Structure
Head/Neck	CT	Quality Improvement	Validation set size	International	Overall AUC	Localized	Free pilot Duration: _____
Breast	MRI	Efficiency	Validation data source	Domestic	FP Rate	Cloud based	Per case
Chest	XR	Triaging	Number of readers	Academic	FN Rate	Processing time	Per user
Cardiac	US	Diagnostic	Definition of ground truth	Community	PPV	Anonymization (local or cloud)	Per workstation





Subspecialty	Modality	Value Proposition	Validation methodology	Data Source	Performance Metrics	Implementation	Cost Structure
Body			Quantitative thresholds used for ground truth (hemorrhage size, nodule size, etc).	Number of sources for training data	NPV	Results displayed as new series	Per Site
MSK/Spine				Scanner/Machine Variability		Results displayed as heat map/other	
Pediatrics						Exports results to dictation software	
Nuclear						Ability to edit findings	





- Home
- Learn
- Define
- Annotate
- Create
- Evaluate
- Run
- Publish
- Assess
- Collaborate
- AI Community

## Define Use Cases

Explore existing use cases for AI in medical imaging, or propose your own idea for a use case.

## Annotate

Create structured data sets around specific AI use cases by annotating images.

## Create

Develop your own AI model for a specific AI use case. Select the use case and the data set, preprocess the images, define the architecture, and train and test your model.



Define Problem



Prepare Data



Configure Model



Train and Test



# ACR AI Lab



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## Run

Run inference on selected cases to test the performance of AI models.

## Evaluate

Compare the performance of two models on the same data set.

## AI Community

Explore ACR AI-LAB™ Ecosystem, Demonstrations, Commercial Participation and Community resources.

## Collaborate

Share models, share datasets, and help crowd-source image annotations.



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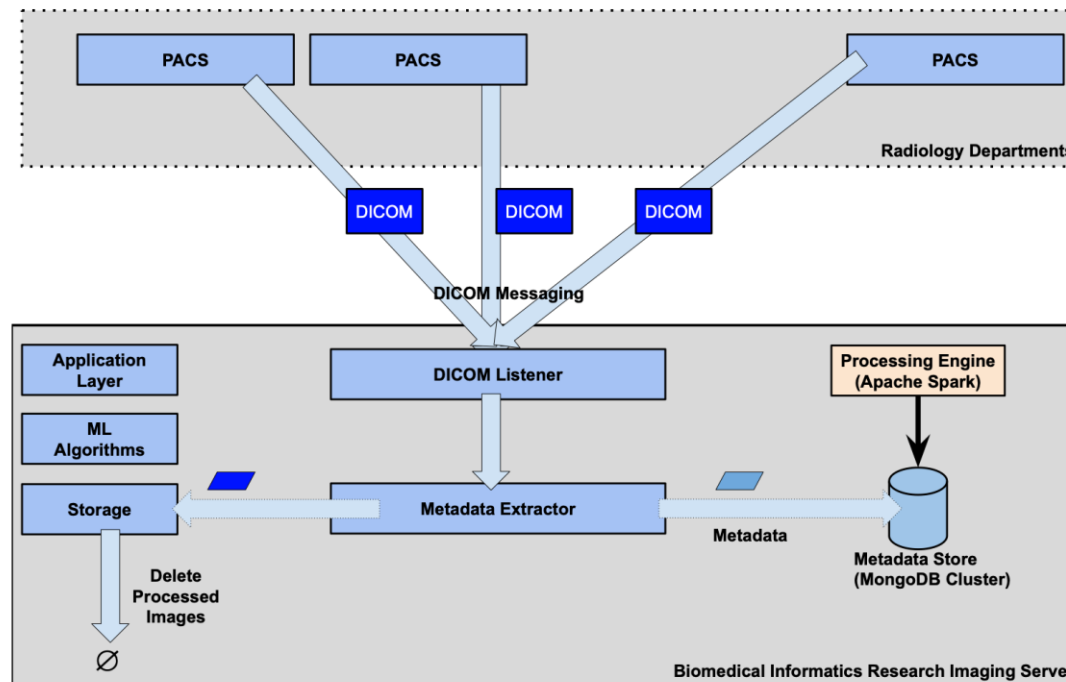
# The Emory Experience - Niffler



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Kathiravelu et al - Developing and Deploying Machine Learning Pipelines against Real-Time Image Streams from the PACS.

# The Emory Experience



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[judywawira@emory.edu](mailto:judywawira@emory.edu)

<http://hitilab.org>



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 @judywawira