Implementation of Medical AI in the Clinical Setting

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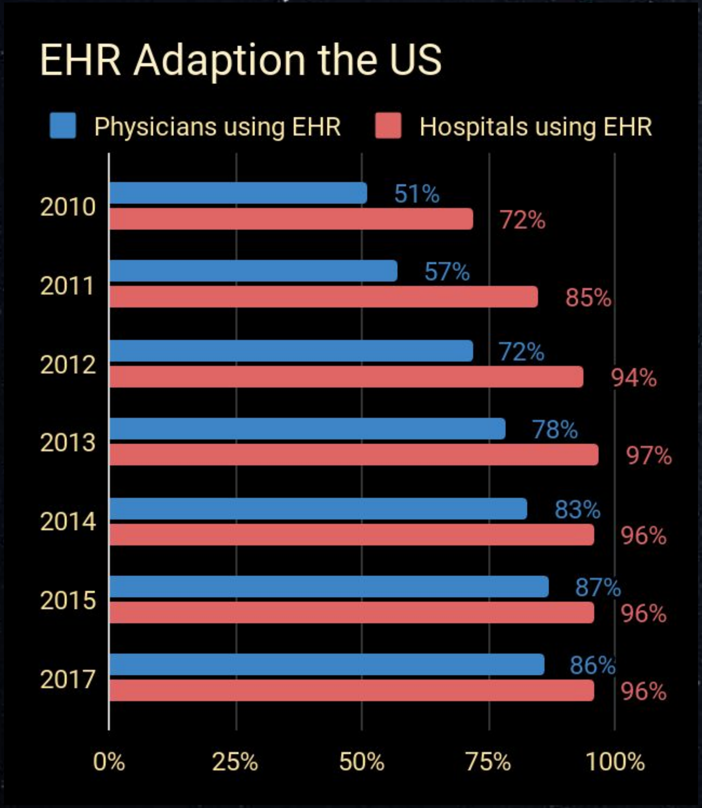
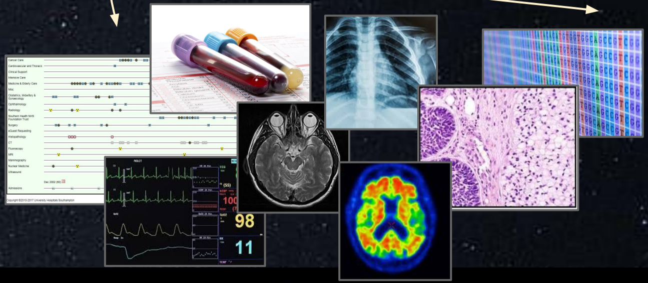
Center for Healthcare Innovation & Delivery Science
Predictive Analytics Unit
Departments of Population Health and Radiology
New York University Langone Health

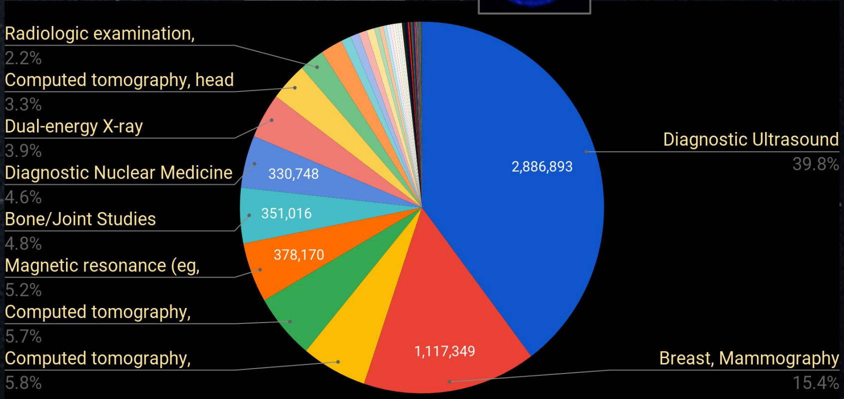
The Healthcare Data Revolution



<u>NYU Langone</u>

8.5 mil Patients since 2013

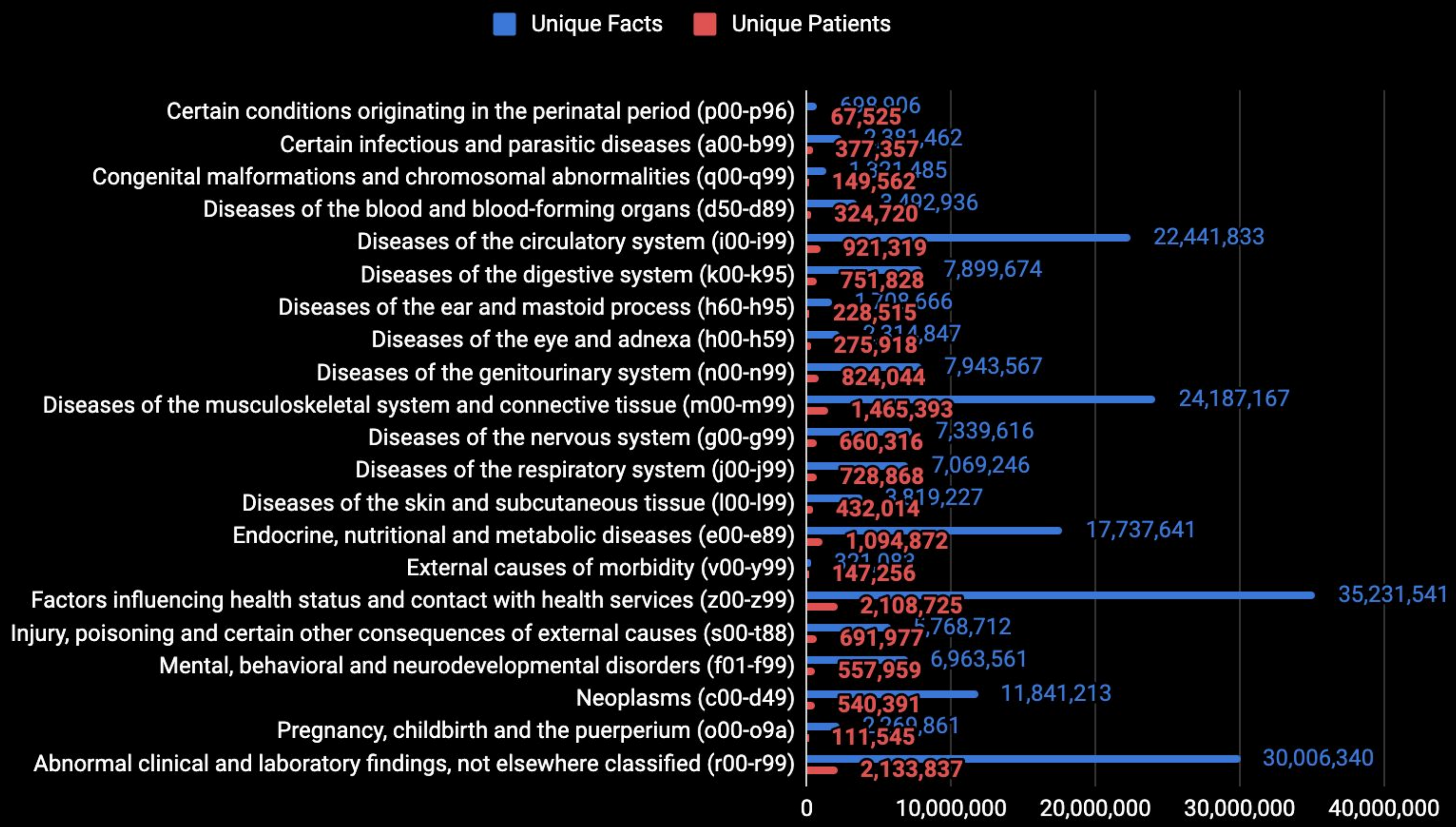




300+ Locations

As of March 2019

NYU Patients and Diseases



Improving Patient Care

Decision Support to Clinicians

Decision Support to Patients

Improving Patient Care

New Data-Driven Guidelines for Medical Societies

Resource Allocation Policies

Improving Patient Care

Decision Support to Clinicians

Lowering diagnostic errors

Aggregating more data

Prognosis

Decision Support to Patients

Adherence

Education

Diagnosis and Prognosis

New Data-Driven Guidelines for Medical Societies

Counterfactual/Causal insights,
Personalized medicine

Screening, Diagnosis and Prognosis

Resource Allocation Policies

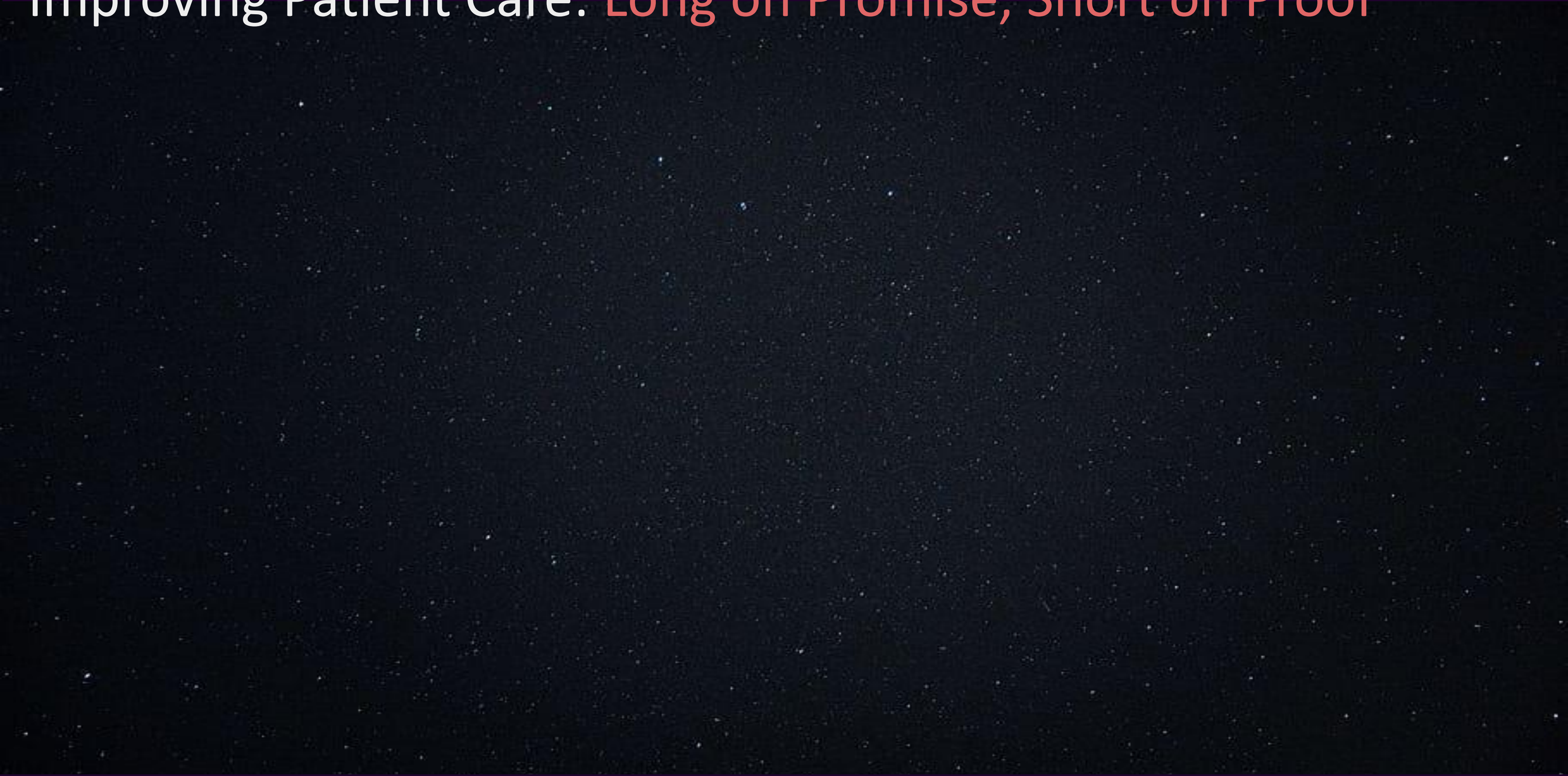
Better planning

Improving Fairness

Automation to Scale

Legislations and Reimbursements

Improving Patient Care: Long on Promise, Short on Proof



Improving Patient Care: Long on Promise, Short on Proof

Comment | Published: 09 September 2020

Welcoming new guidelines for AI clinical research

Eric J. Topol

Nature Medicine **26**, 1318–1320(2020) | Cite this article

6802 Accesses | **6** Citations | **239** Altmetric | Metrics

With only a limited number of clinical trials of artificial intelligence in medicine thus far, the first guidelines for protocols and reporting arrive at an opportune time. Better protocol design, along with consistent and complete data presentation, will greatly facilitate interpretation and validation of these trials, and will help the field to move forward.

The past decade ushered in excitement for the potential to apply deep-learning algorithms to healthcare. This subtype of artificial intelligence (AI) has the ability to improve the accuracy and speed of interpreting large datasets, such as images, speech and text. However, for deep learning to be accepted and implemented in the care of patients, proof from randomized clinical trials is urgently needed.

Of hundreds of retrospective AI models, only a dozen prospective trials and 7 RCTs (6 in China)

Article | Open Access | Published: 06 October 2020

A validated, real-time prediction model for favorable outcomes in hospitalized COVID-19 patients

Narges Razavian, Vincent J. Major, Mukund Sudarshan, Jesse Burk-Rafel, Peter Stella, Hardev Randhawa, Seda Bilaloglu, Ji Chen, Vuthy Nguy, Walter Wang, Hao Zhang, Ilan Reinstein, David Kudlowitz, Cameron Zenger, Meng Cao, Ruina Zhang, Siddhant Dogra, Keerthi B. Harish, Brian Bosworth, Fritz Francois, Leora I. Horwitz, Rajesh Ranganath, Jonathan Austrian & Yindalon Aphinyanaphongs

npj Digital Medicine **3**, Article number: 130 (2020) | Cite this article

5243 Accesses | **1** Citations | **55** Altmetric | Metrics

Of 30 Peer-reviewed COVID models, 1 underwent prospective validation and none underwent an RCT

nature > nature machine intelligence > analyses > article

Analysis | Open Access | Published: 15 March 2021

Common pitfalls and recommendations for using machine learning to detect and prognosticate for COVID-19 using chest radiographs and CT scans

Michael Roberts, Derek Driggs, Matthew Thorpe, Julian Gilbey, Michael Yeung, Stephan Ursprung, Angelica I. Aviles-Rivero, Christian Etmann, Cathal McCague, Lucian Beer, Jonathan R. Weir-McCall, Zhongzhao Teng, Effrossyni Gkrania-Klotsas, AIX-COVNET, James H. F. Rudd, Evis Sala & Carola-Bibiane Schönlieb

Nature Machine Intelligence **3**, 199–217(2021) | Cite this article

16k Accesses | **786** Altmetric | Metrics

Zero out of 62 reviewed Covid Imaging work has been implemented or even suitable in any clinical practice

AI Implementation: The Full Process

AI Implementation: The Full Process

Clinical Problem

Wide Adoption

AI Implementation: The Full Process

1. Clinical Problem
2. Inclusion Exclusion Input Output
3. Data & IP
4. AI Modeling & *Retrospective* Validation
5. Deployment infrastructure
6. *Prospective* Validation
7. Regulatory Approvals & Continuous Monitoring
8. Educating Clinicians & Users
9. RCT to Assess Added Value
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11. Update Clinical Guidelines
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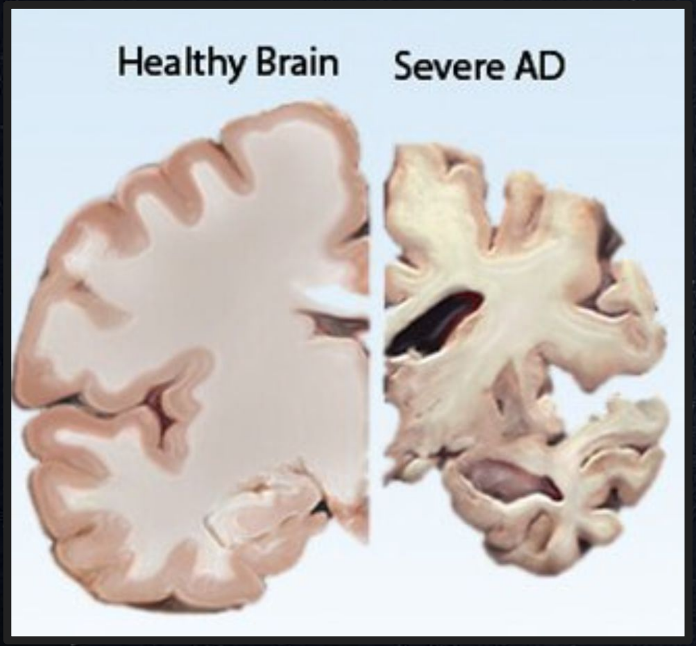

Development and Validation of a Deep Learning Model for Early Alzheimer's Detection from Structural MRIs

Sheng Liu, Arjun Masurkar, Henry Rusinek, Jingyun Chen, Ben Zhang, Weicheng Zhu, Carlos Fernandez-Granda and Narges Razavian

Nature Scientific Reports, 2022

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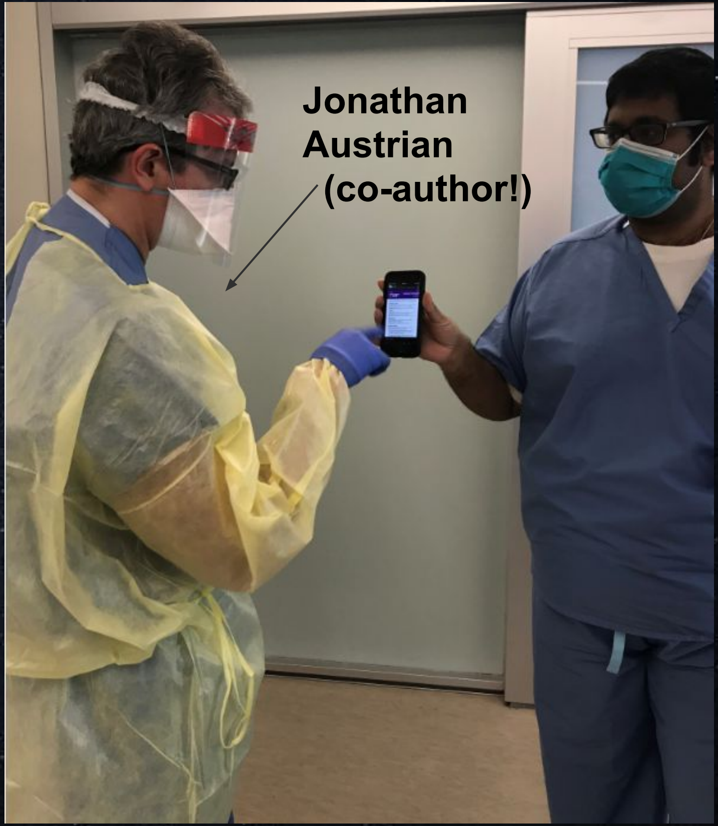
Covid-19

Unknown Disease Trajectories

- Research from China/Italy
- NEJM, CDC, Ever-changing info

How could AI help?

- Who is likely to have a positive test?
- Who should be admitted from the ED?
- Who is likely to deteriorate on the floors?
- Who is likely to be safe to discharge from the hospital?



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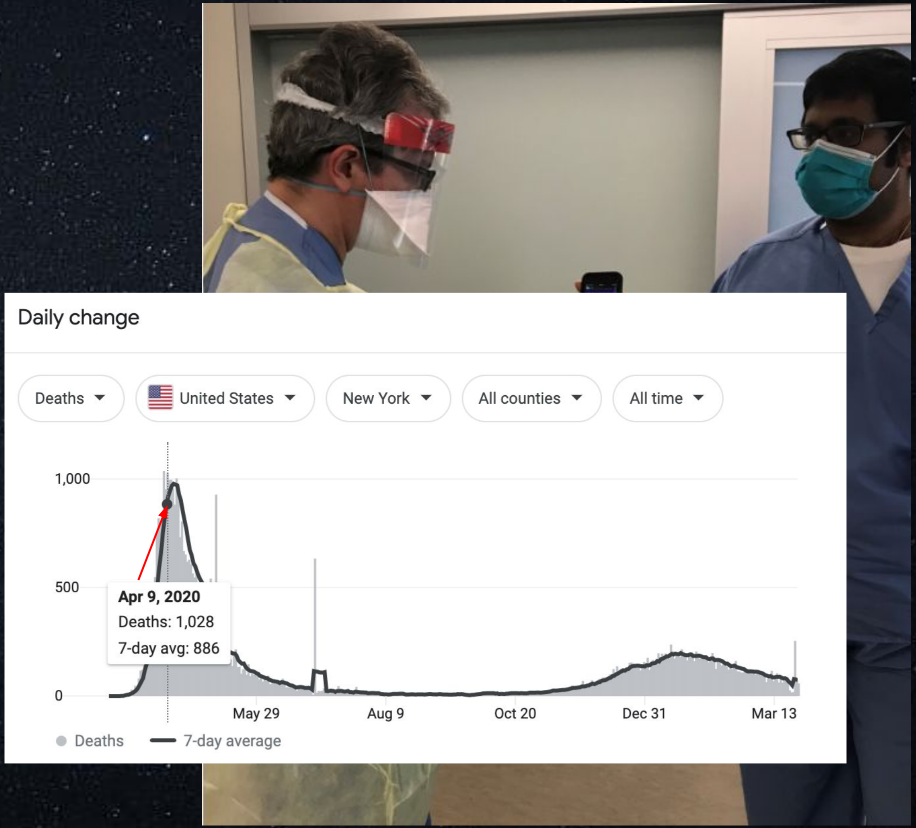
Most Actionable Task:

Who is likely to be *safe to discharge?*

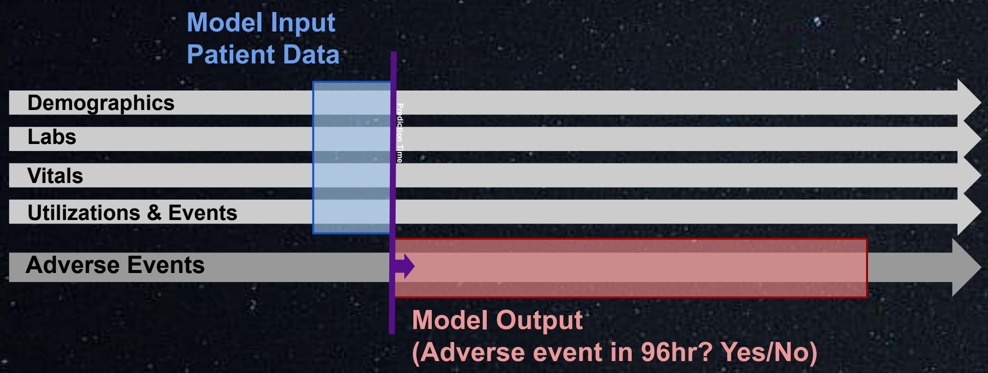


Covid-19

Who is likely to be safe to discharge?

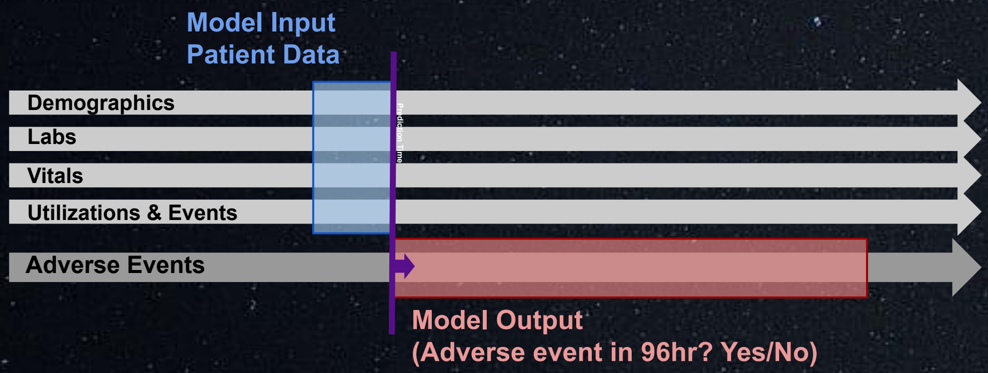
Covid-19

Who is likely to be safe to discharge?



Covid-19

Who is likely to be safe to discharge?



1. ICU transfer
2. Intubation
3. ED representation
4. Hospice discharge
5. Mortality
6. Requiring O2 support in excess of nasal cannula at 6 L/min.

Covid-19

Model needed to be put into EPIC

Covid-19

Model needed to be put into EPIC

Powerful model trained on all available inputs

Variable selection: Yields p-values for importance of each input

Build parsimonious model with only important variables

Covid-19

Model needed to be put into EPIC

Powerful model trained on all available inputs

Variable selection: Yields p-values for importance of each input

Build parsimonious model with only important variables

65 variables:
demographics, vital signs, laboratory results, O2 utilization variables, and length-of-stay up to prediction time

→

13 variables
Oxygen support device, respiratory rate, oxygen saturation, temperature, LDH, platelet count, blood urea nitrogen, C-reactive protein, heart rate, eosinophils%

Covid-19

Model needed to be put into EPIC

Powerful model trained on all available inputs

Variable selection: Yields p-values for importance of each input

Build parsimonious model with only important variables

Training: 1990 patients
17,614 prediction instances

Validation: 663 patients,
4,903 prediction instances

Heldout: 664 patients, 5914 prediction instances

<u>“Blackbox” Models:</u>
LightGBM
Random Forest
Logistic Regression
Ensemble of all 3

<u>Parsimonious Model:</u>
Logistic Regression

Covid-19

Model needed to be put into EPIC

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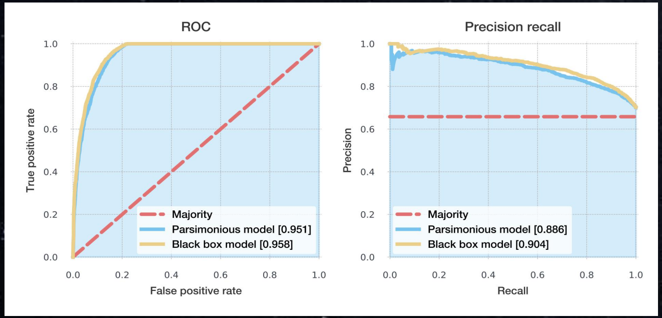

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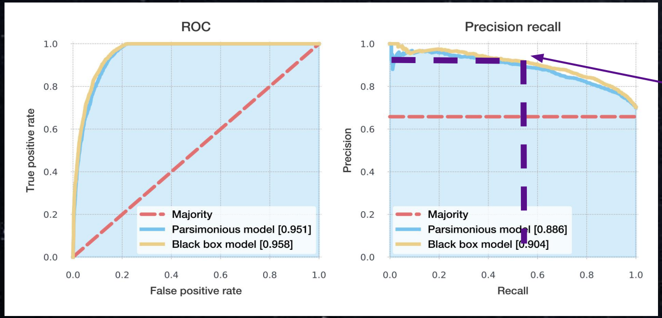
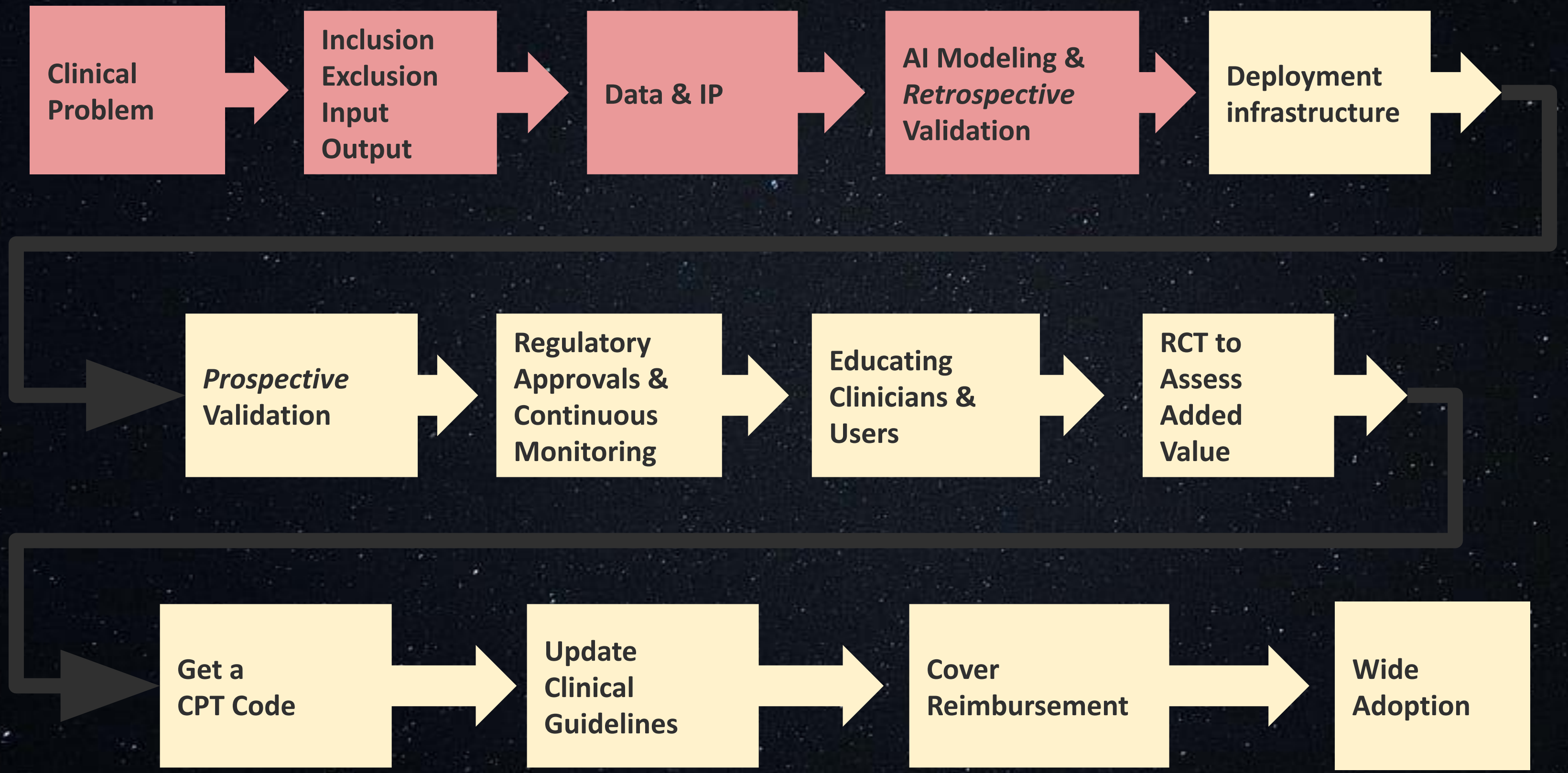


Threshold set for:
90% PPV
54.2% Sensitivity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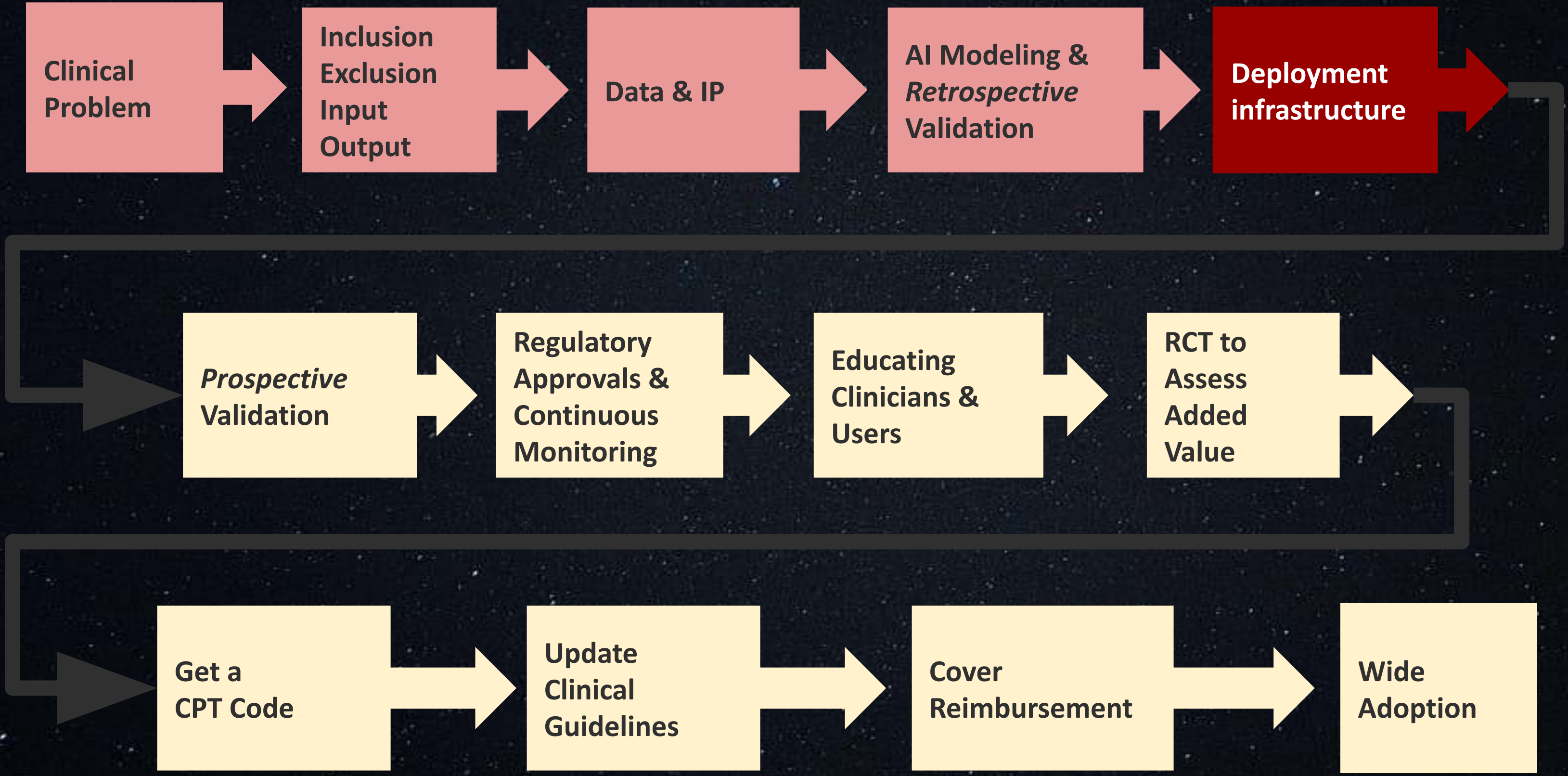
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Retrospective vs. Prospective Validation

Live data lives in Chronicles DataBase

By midnight - Clarity DB syncs with Chronicles

- Mortality, ICU, deterioration for retrospective modeling came from Clarity DB

By 7AM daily - Caboodle DB syncs with Clarity

- Labs, Covid tests & results, ED and inpatient times, flowsheets: vitals, O2 vol/devices (for retrospective modeling)

Team
Yin Aphinyanaphongs
Nader Mherabi
Jonathan Austrian
Paul Testa
Eduardo Iturrate
Rajan Chandras
Jordan Swartz
Vincent Major
Narges Razavian
Ji Chen
Neil Jethani
Jager Hartman
Jie Yang
Seda Bilaloglu
Ben Zhang
Po Lai Yau
Walter Wang
Vuthy Nguy
Po Lai Yau
Michael Quinn
Hao Zhang
Rajesh Ranganath
Mukund Sudarshan

Deployment

Intended use: live, update every 30 minute

"Reporting workbench" to select variables & inclusion/exclusion criteria from Chronicles directly. (Tedious job!)

Model via *Nebula* cloud computing platform (Python)

Results pushed back into "Patient List" and "Covid Summary Report". Stored as flowsheet

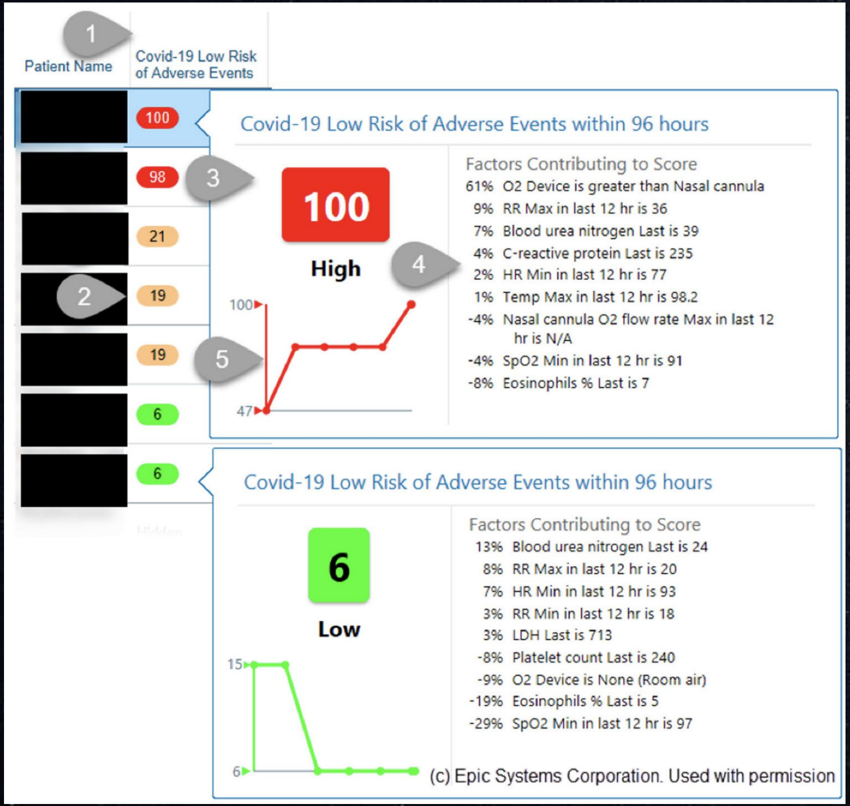
Can show "variable contributions" to model score

Team

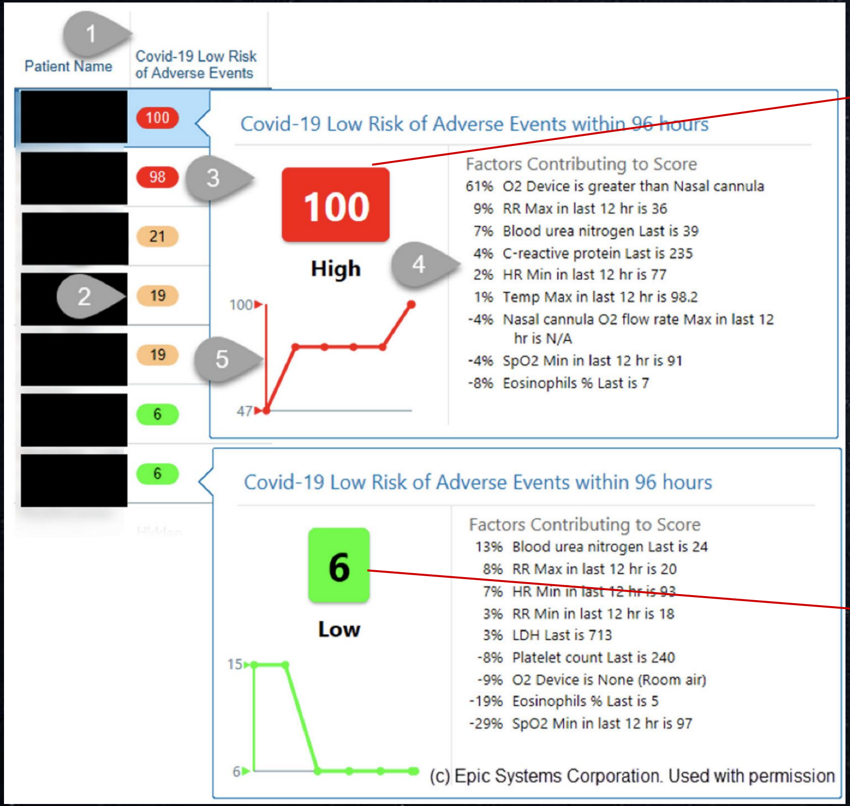
NYU
Yin Aphinyanaphongs
Jonathan Austrian
Vincent Major

EPIC
Adrienne Alimasa
Garry Bowlin
Erin Ello
Nick Krueger
Sean McGunigal
Joe McNitt
Ben Noffke
George Redgrave
Owen Sizemore
Drew McCombs
James Hickman

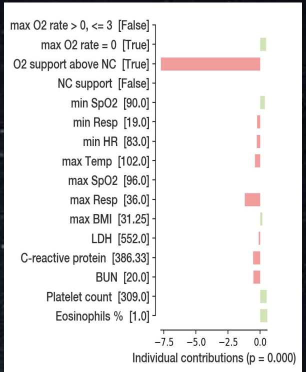
What Clinicians See in Patient Lists

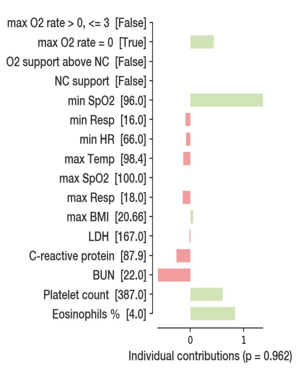


What Clinicians See in Patient Lists

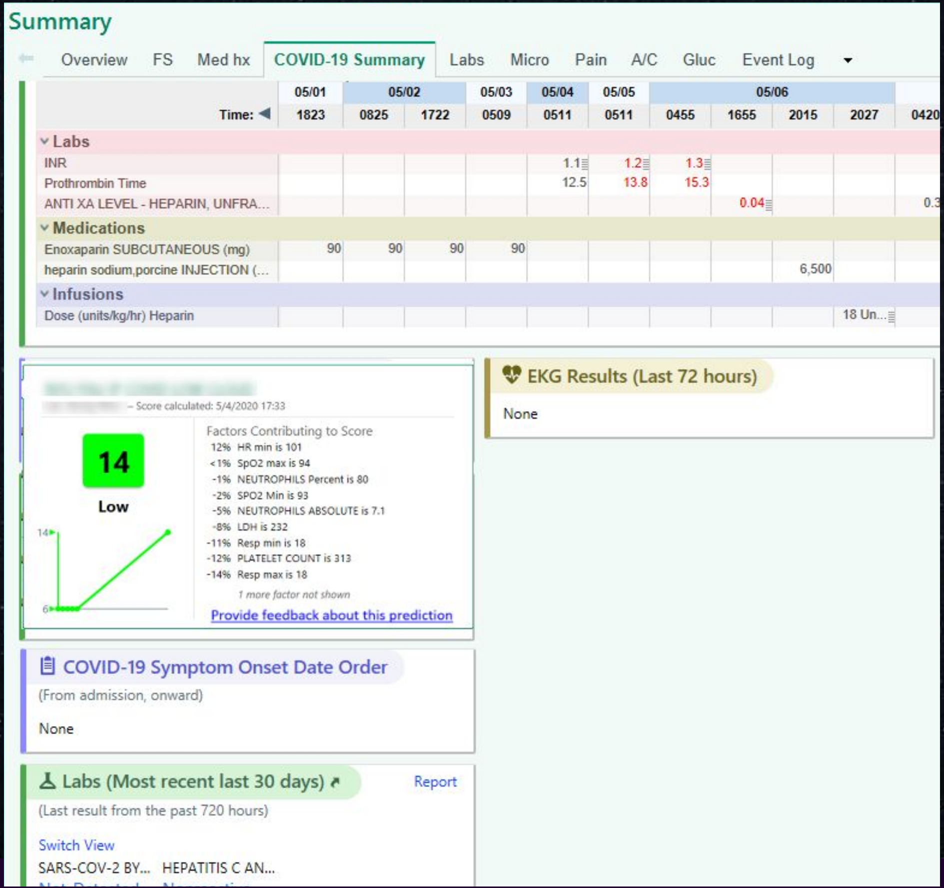


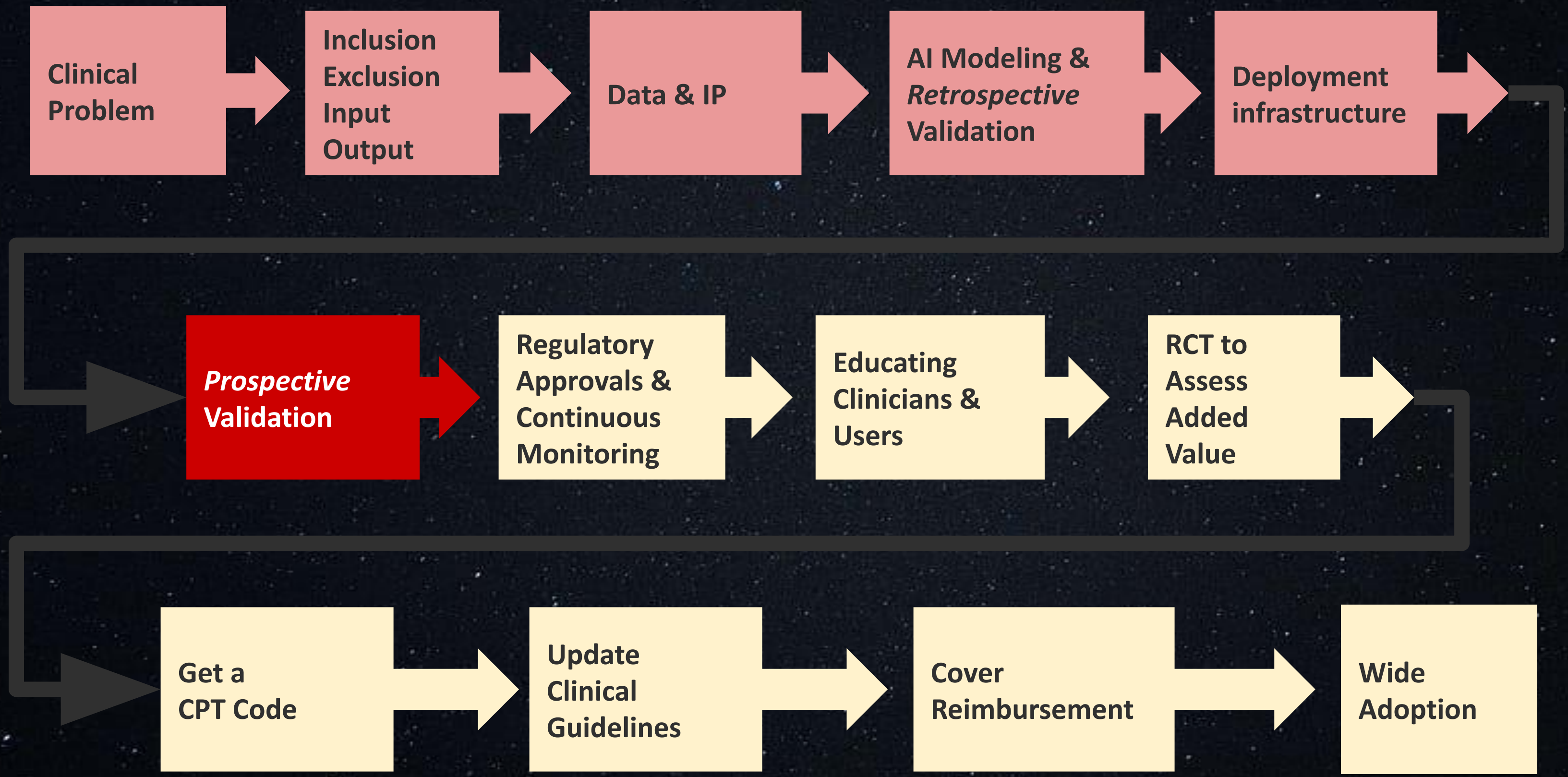
Variable Contributions Viewable by hovering





What Clinicians See in “Covid Summary Report”

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Prospective Validation

Silent live (May 1 - May 15)

- Chart review by clinical team
- Setting up randomization for RCT
- Monitoring infrastructure

Live on Friday May 15th 2020

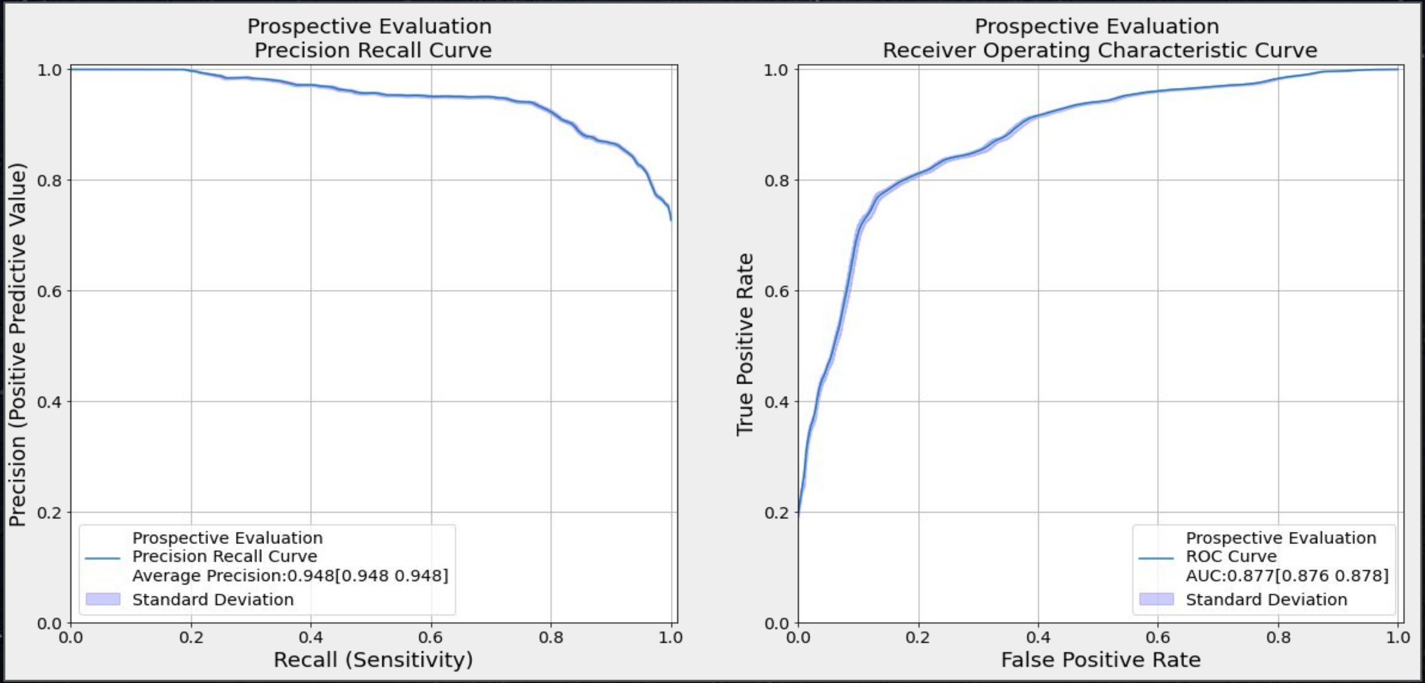
- Outreach via broadcast email
- Outreach via campus-wide presentations
- Clinician education, QA
- Continuous monitoring
- Chart review of all re-admissions and all mortality (regardless of RCT arm)

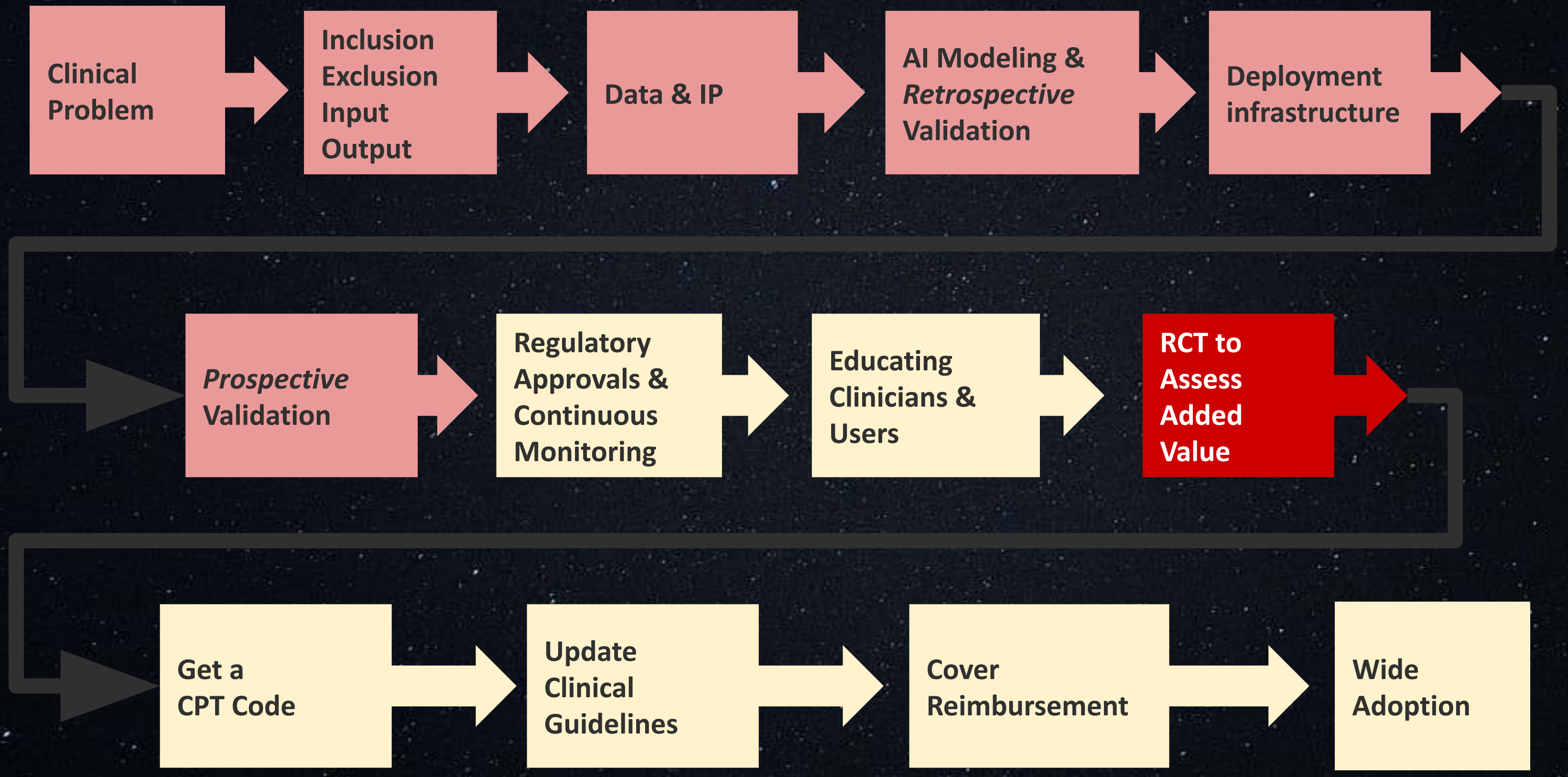
Team

Jonathan Austrian
Yin Aphinyanaphongs
Vincent Major
Nader Mherabi
Brian Bosworth
Fritz Francois
Jesse Rafel
David Kudlowsky
Peter Stella
Simon Jones
Walter Wang
Vuthy Nguy
Cameron Zenger
Julia Greenberg
Meng Cao
Ruina Zhang
Sid Dogra

Prospective Validation

Continuous Monitoring & chart review of every re-admission → No harm observed





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Randomized Clinical Trial

Hypothesis:

As patients go green, the care team can prioritize discharge planning leading to a reduction in LOS and the time from first green and discharge.

Intervention:

Display calculated score for half the patients

Outcome:

Primary: Time from first low risk prediction to discharge (gLOS)

Secondary: Length of Stay

Secondary: Readmissions; Re-presentation to the ED within 30 days; Mortality (safety)

<u>Team</u>
Leora Horwitz
Vincent Major
Simon Jones
Ashley Bagheri
Jonathan Austrian
Yin Aphinyanaphongs
Narges Razavian
Peter Stella
Walter Wang
Vuthy Nguy
Michael Quinn
Batia Wiesenfeld
Elisabeth Wang
Jay Stadelman
Felicia Mendoza

Pre-Register the RCT

U.S. National Library of Medicine

ClinicalTrials.gov

Find Studies ▾ About Studies ▾ Submit Studies ▾ Resources ▾ About Site ▾ PRS Login

Home > Search Results > Study Record Detail

Save this study

Predicting Favorable Outcomes in Hospitalized Covid-19 Patients

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Know the risks and potential benefits of clinical studies and talk to your health care provider before participating. Read our disclaimer for details.

ClinicalTrials.gov Identifier: NCT04570488

Recruitment Status : Recruiting
First Posted : September 30, 2020
Last Update Posted : October 14, 2020

See **Contacts and Locations**

Sponsor:
NYU Langone Health

Information provided by (Responsible Party):
NYU Langone Health

Summary of RCT Results

From May to January 2021:

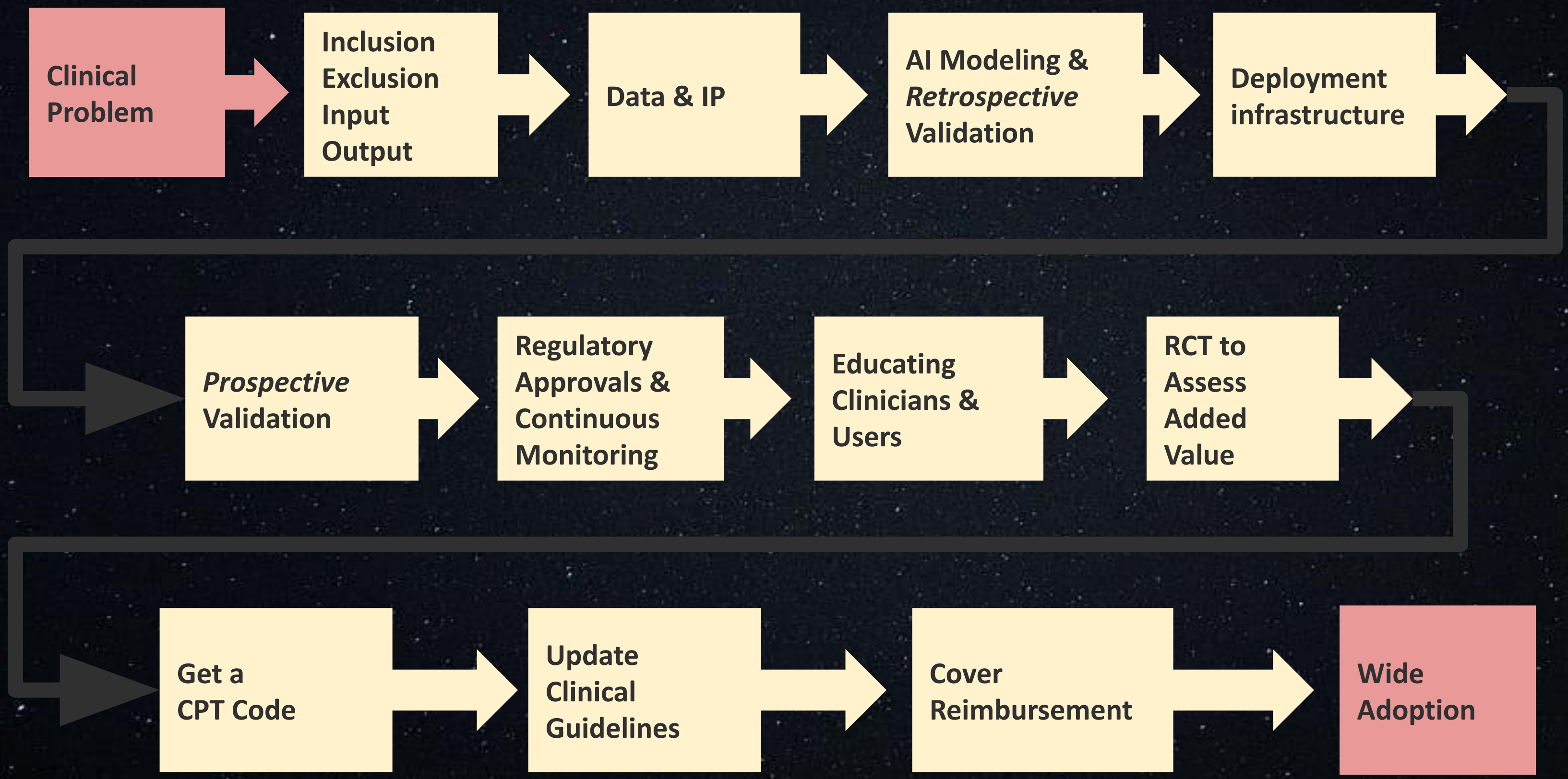
- 1803 admissions
- 1004 with at least 1 green score
- No statistical significance drop in gLOS
  - Intervention: 3.60 [1.95–6.55] vs. Control: 3.83 [2.06, 6.96], p=0.4
  - Effect seems to be isolated to first 10 weeks of the study:
    - Intervention: 3.11 [1.83–5.11] vs. Control: 3.66 [1.98–6.02], p=0.1
  - Past 10 week:
    - Intervention: 4.18 [2.15–10.00] vs. Control: 4.18 [2.17–8.95]
- No impact on safety indicators
  - Any indicator among 1737 patients with >30 days follow-up: 26.7 vs 26.3%, p=0.9

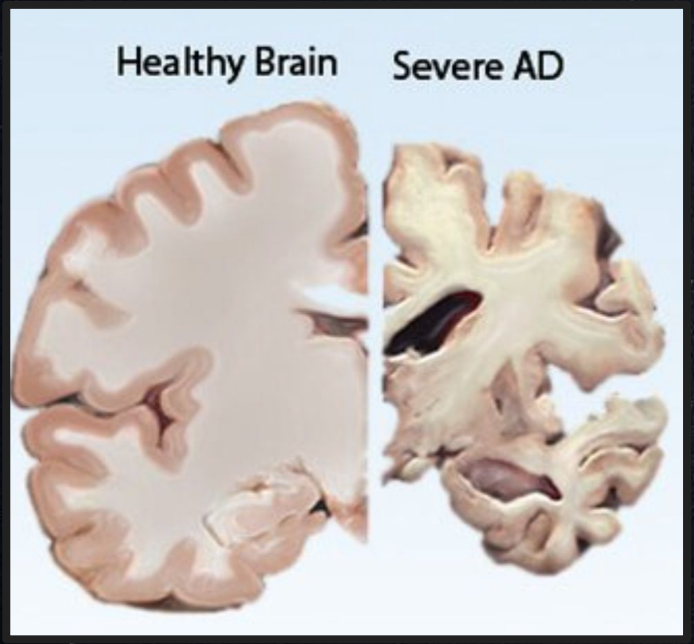
Qualitative Study - Survey of Clinicians

Team
Batia Wiesenfeld
Elisabeth Wang

- 195 Clinicians (attendings) surveyed
- Tool users experienced significantly less uncertainty about treating Covid patients
    - (1-5 scale) $M_{users}=1.89$ vs $M_{non\text{-}users}=2.32$ $p<0.05$
- Tools users reported significantly greater ability to anticipate, plan and prepare for Covid patient discharge
    - (1-5 scale) $M_{users}=2.88$ vs $M_{non\text{-}users}=2.21$ $p<0.1$
- Significant indirect effect of tool use on confidence in a safe discharge via increased ability to anticipate, plan and prepare for discharge
- Tool experienced as generally consistent with clinical judgement
- Experienced as most valuable early in pandemic (higher overload/pressure to discharge/uncertainty/inexperience)
- When tool is discrepant from clinician's judgment, clinicians report investigating case further - increasing learning/improved decision making
- Primary barriers to tool use: Lack of awareness/education/validation information

AI Implementation: The Full Process





Development and Validation of a Deep Learning Model for Early Alzheimer's Detection from Structural MRIs

Sheng Liu, Arjun Masurkar, Henry Rusinek, Jingyun Chen, Ben Zhang, Weicheng Zhu, Carlos Fernandez-Granda and Narges Razavian

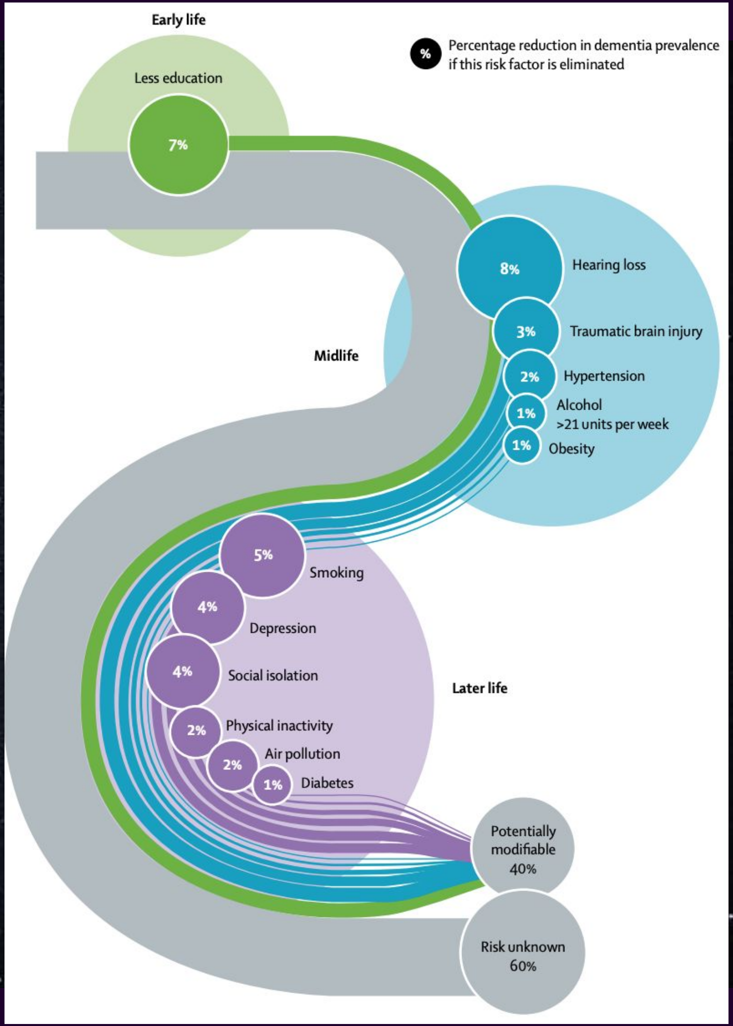
Nature Scientific Reports, 2022

Early Detection Matters

- All new clinical trials address “Mild to moderate AD”
- Early detection for preventative care
  - SPRINT MIND large scale randomized trial: Intensive hypertension control helps prevent conversion to MCI/AD
  - PREVENTABLE trial underway to study statins & cholesterol control
- Improved caregiver support & financial planning
- Better enrollment for clinical trials

Dementia Disease Disparities

- 66% of AD patients are women
- Risk factors correlate with Race & Socio-economic status
- Black and Hispanic patients 30% and 40% less likely than White patients to be seen by neurologists
    - ower education, low income, and being uninsured → lower neurologist visits
- Dementia screening instruments (MOCA, MMSE) & tools build on majority white research cohorts
    - eRADAR (2 current NIH R01s) on 90% White population
    - NACC National Alzheimer's Coordination Center (83% White)
    - ADNI Alzheimer's Disease Neuroimaging Initiative 48 (92% White)



Imaging Biomarkers

PET imaging with β-amyloid & Tau tracers → Not covered by insurance, expensive, different non-standardized tracers (tau)

Structural MRIs

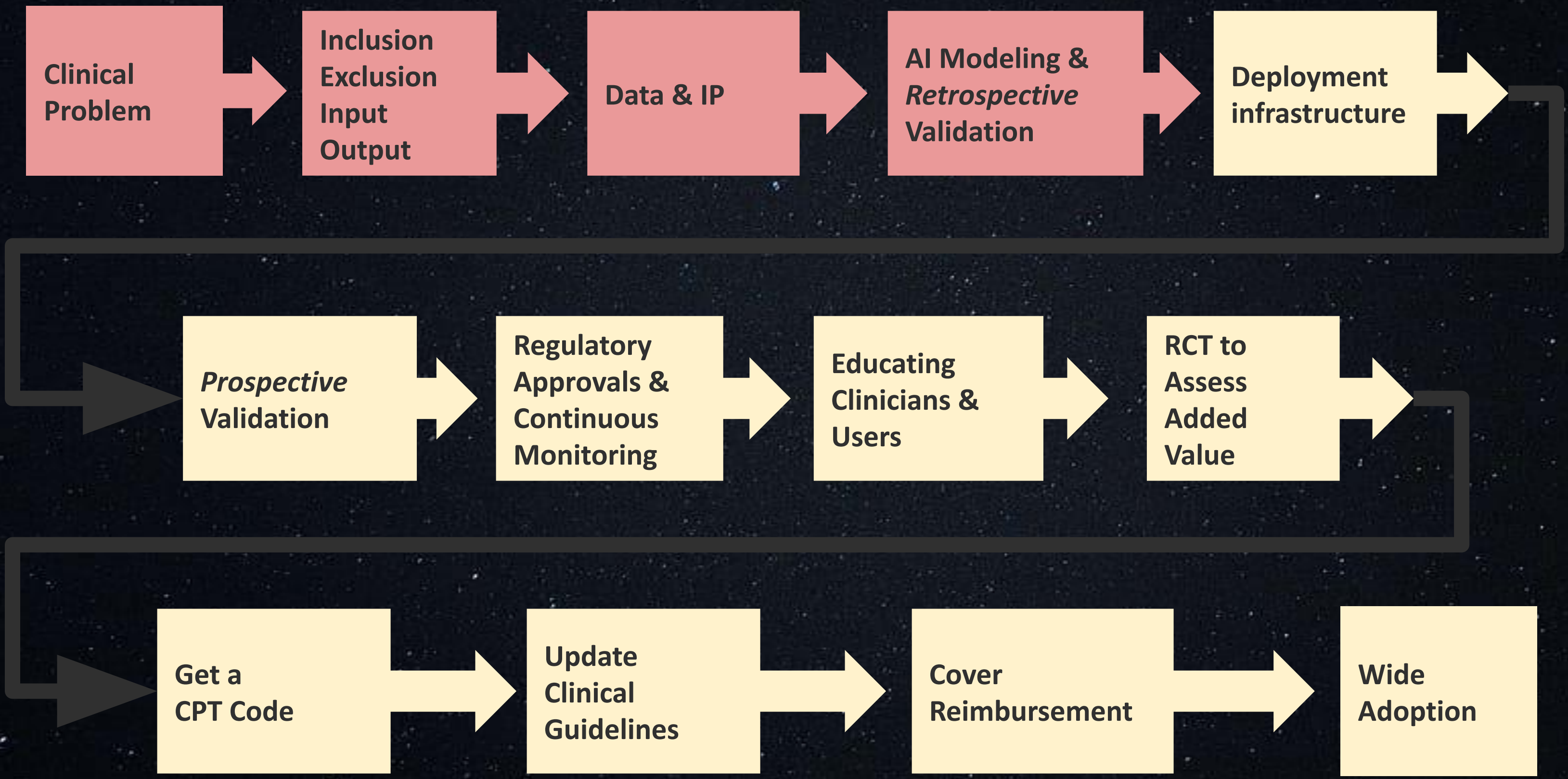
→ Show atrophies

→ Historically using hippocampal volume (not accurate at MCI stage).

→ Can we use deep learning on 3D volumes to better identify?

→ Can we integrate these models into clinical settings and measure their impact?

→ Do the model eventually change patient outcome (i.e. rate of early detection)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Data - Publicly available large cohorts from NIH/NIA

Alzheimer's Disease NeuroImaging Initiative (ADNI)

- Longitudinal multicenter study designed to develop clinical, imaging, genetic, and biochemical biomarkers for the early detection and tracking of Alzheimer's disease
- 652 individuals with T1 MRIs
  - 2619 MRI scans

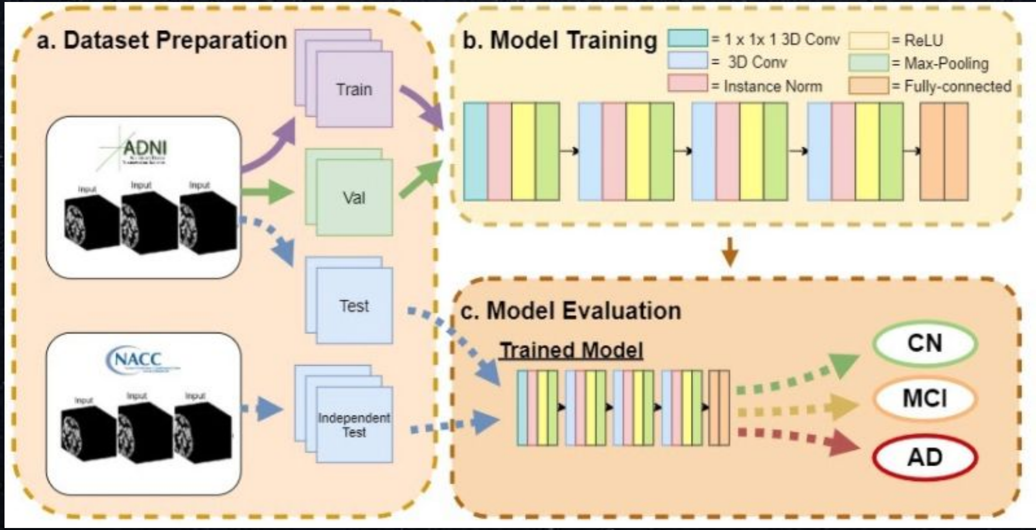
National Alzheimer's Coordinating Center (NACC)

- Established in 1999, is a large relational database of standardized clinical and neuropathological research data
- 1522 individuals with T1 MRIs
  - 2045 MRI scans

Model Architecture

Improved architecture via

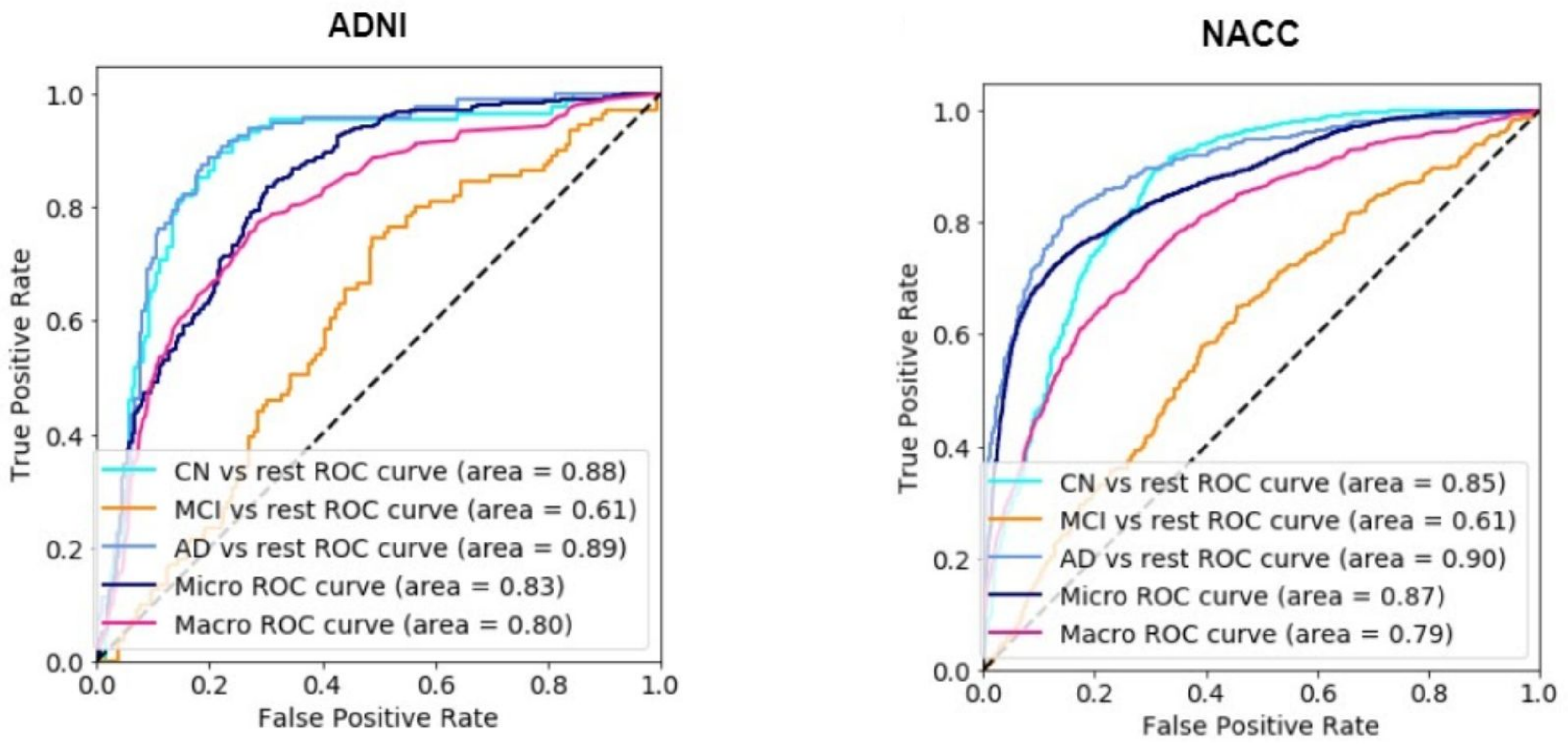
- Instance normalization outperforms Batch normalization
- Less early spatial downsampling
- Widening the layers brings consistent gains while increasing the depth does not



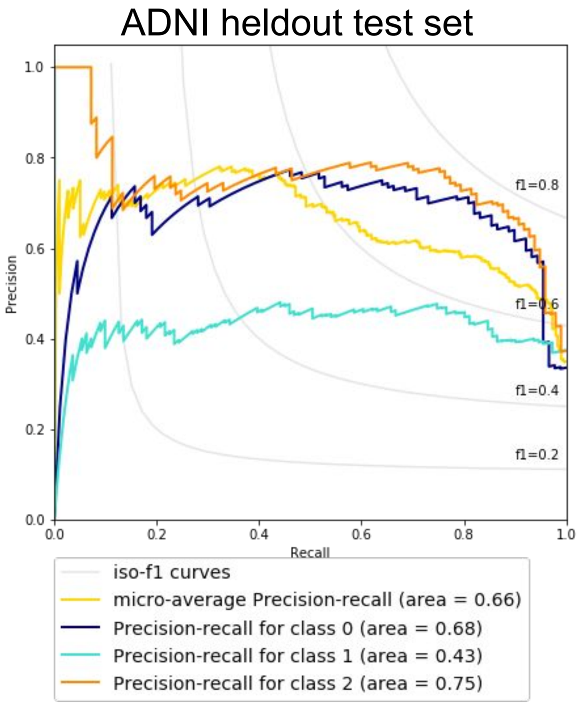
Characteristics Table

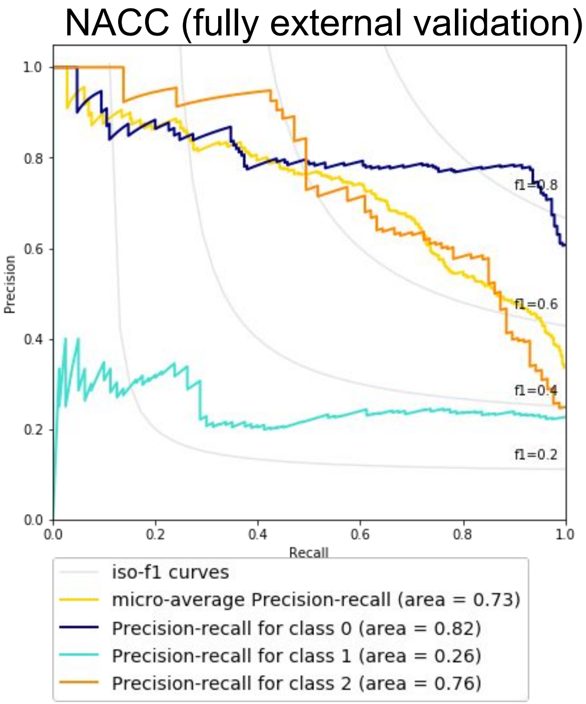
	ADNI (n=2619)			NACC (n=2025)		
Patient Characteristics	**Cognitively Normal (n =782)**	**Mild Cognitive Impairment (n=1089)**	**Alzheimer's Disease (n=748)**	**Cognitively Normal (n=1281)**	**Mild Cognitive Impairment (n = 322)**	**Alzheimer's Disease (n = 422)**
Age, mean (sd)	77.3 (5.6)	76.5 (7.3)	76.5 (7.3)	69.1 (9.4)* (p-val<0.01)	74.4 (8.5)* (p-val<0.01)	73.9 (8.8)* (p-val:<0.01)
Sex, n (%)						
Male	394 (50.4%)	659 (60.5%)	406 (54.3%)	489 (38.2%)* (p-val<0.01)	128 (39.8%)* (p-val<0.01)	219 (49.5%) (p-val:0.433)
Female	388 (49.6%)	430 (39.5%)	342 (45.7%)	792 (61.8%)* (p-val<0.01)	194 (60.2%)* (p-val<0.01)	223 (50.5%)* (p-val:0.02)
Education, avg years (sd)	17.2 (3.1)	16.7 (3.2)	16.1 (3.5)	16.3 (2.6)* (p-val<0.01)	15.7 (2.8)* (p-val<0.01)	15.1 (3.3)* (p-val<0.01)
APOE4, n (%)	224 (28.6%)	567 (52.1%)	496 (66.3%)	479 (37.4%)* (p-val<0.01)	146 (45.3%)* (p-val:0.03)	202 (45.7%)* (p-val<0.01)

Results

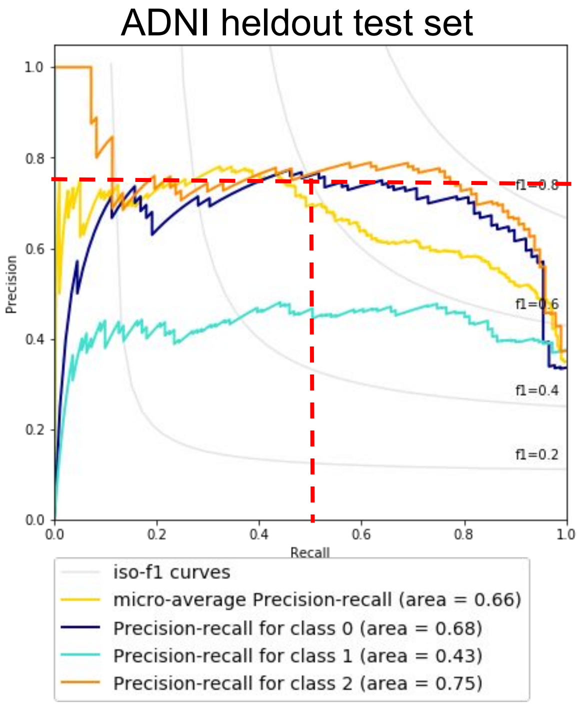

ADNI
True Positive Rate
False Positive Rate
CN vs rest ROC curve (area = 0.88)
MCI vs rest ROC curve (area = 0.61)
AD vs rest ROC curve (area = 0.89)
Micro ROC curve (area = 0.83)
Macro ROC curve (area = 0.80)
NACC
True Positive Rate
False Positive Rate
CN vs rest ROC curve (area = 0.85)
MCI vs rest ROC curve (area = 0.61)
AD vs rest ROC curve (area = 0.90)
Micro ROC curve (area = 0.87)
Macro ROC curve (area = 0.79)

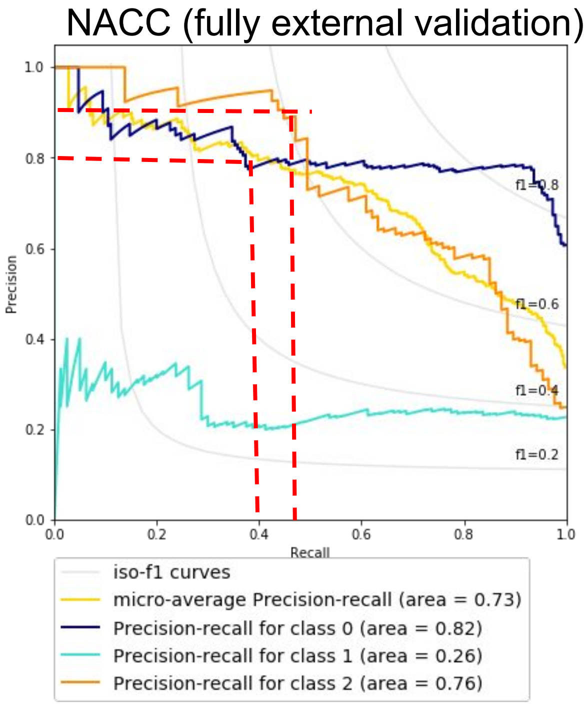
Precision/Recall Curves - Clinically Actionable





Precision/Recall Curves - Clinically Actionable





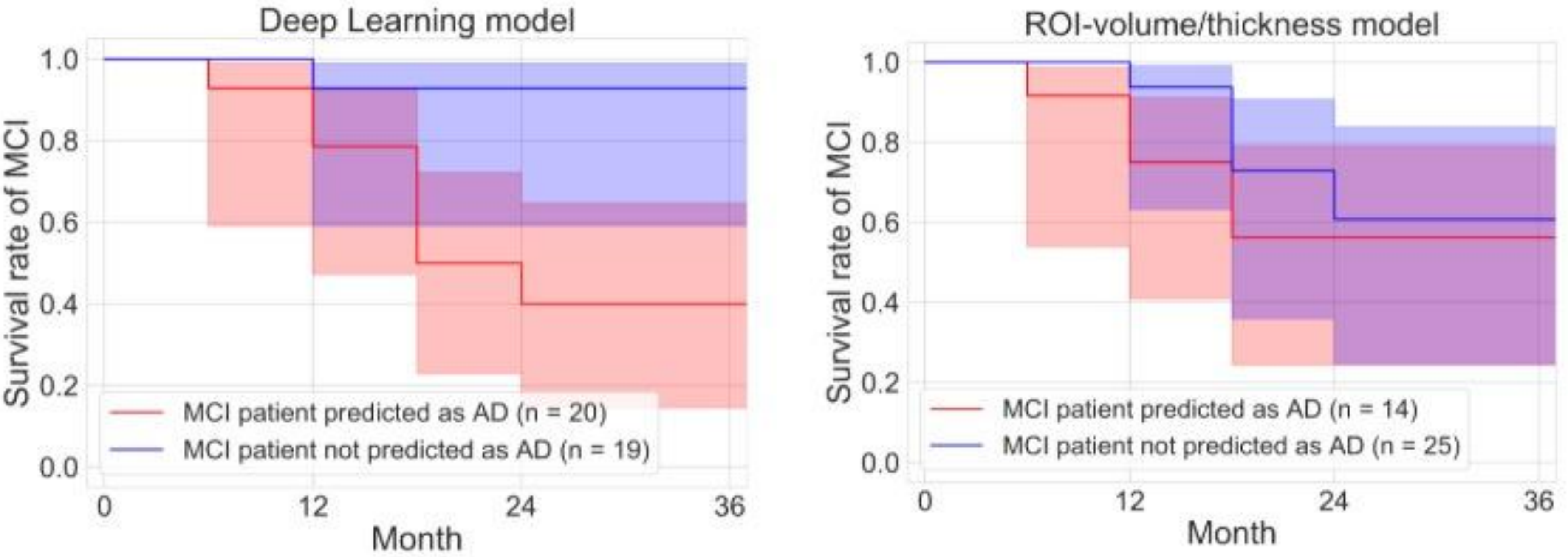
How does deep learning compare to Freesurfer based model?

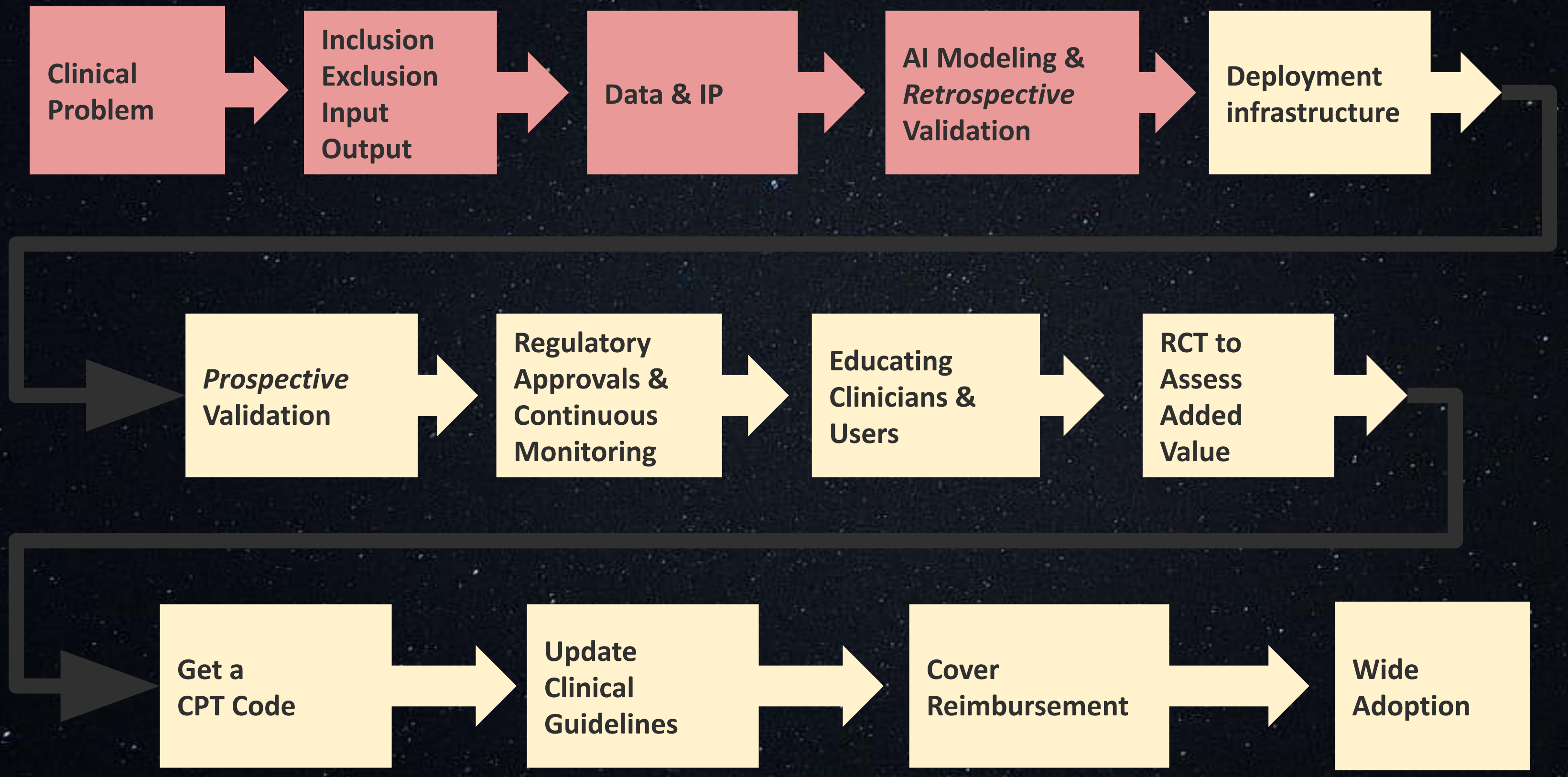
	ADNI Heldout (n=90 individuals, 297 scans)		NACC external validation (n=1522 individuals, 2025 scans)	
	Deep learning model Area under ROC curve	Freesurfer-based model Area under ROC curve	**Deep learning model Area under ROC curve**	Freesurfer-based model Area under ROC curve
Cognitively Normal	**87.59 (95% CI: 87.13 - 88.05)**	84.45 (95% CI: 84.19 - 84.71)	**85.12 (95% CI: 85.26 - 84.98)**	80.77 (95% CI: 80.55 - 80.99)
Mild Cognitive Impairment	**62.59 (95% CI: 62.01 - 63.17)**	56.95 (95% CI: 56.27 - 57.63)	**62.45 (95% CI: 62.82 - 62.08)**	57.88 (95% CI: 57.53 - 58.23)
Alzheimer's Disease Dementia	**89.21 (95% CI: 88.88 - 89.54)**	85.57 (95% CI: 85.16 - 85.98)	**89.21 (95% CI: 88.99 - 89.43)**	81.03 (95% CI: 80.84 - 81.21)

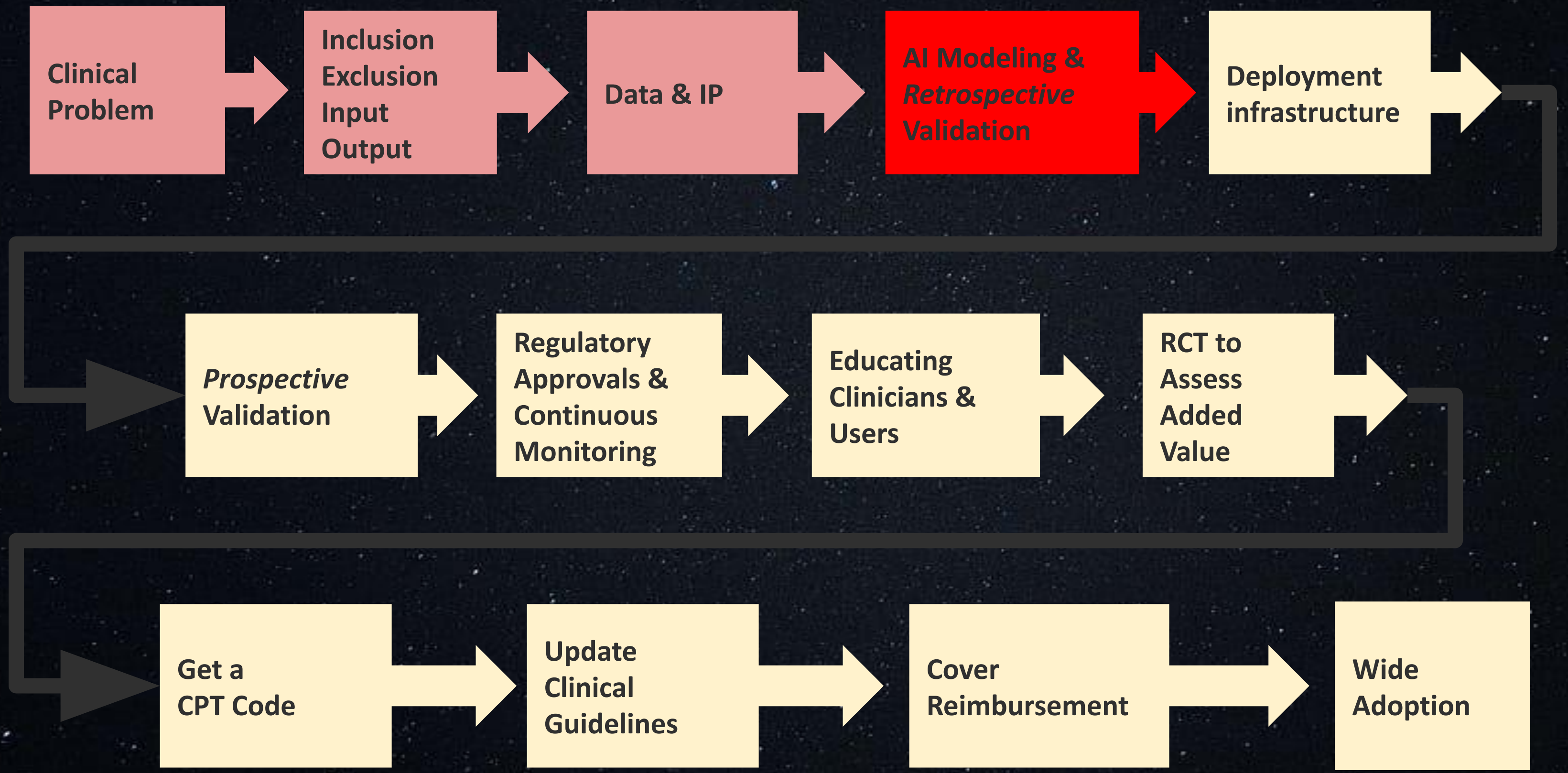
Freesurfer also takes **11 hours** per MRI vs. Deep learning model that takes **7.8mins** (7 min of pre-processing, 0.07s of the model running)

Progression to Dementia

For MCI patients predicted as AD vs not AD




Clinical Problem
Inclusion Exclusion Input Output
Data & IP
AI Modeling & *Retrospective* Validation
Deployment infrastructure
Prospective Validation
Regulatory Approvals & Continuous Monitoring
Educating Clinicians & Users
RCT to Assess Added Value
Get a CPT Code
Update Clinical Guidelines
Cover Reimbursement
Wide Adoption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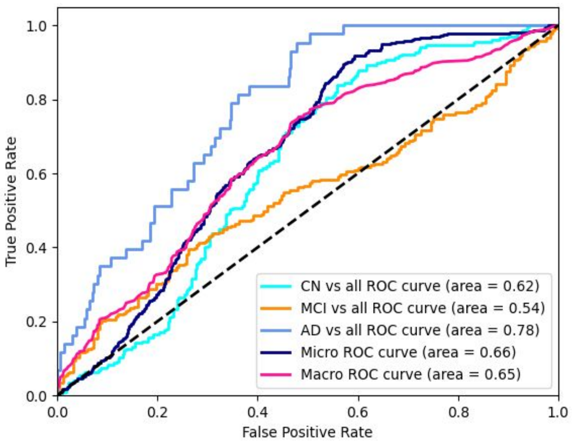
Clinical MRI data from NYU Barlow Memory Center (NIH Designated AD research center ADRC) (Patients who visited 10 neurologists there and had MRIs)

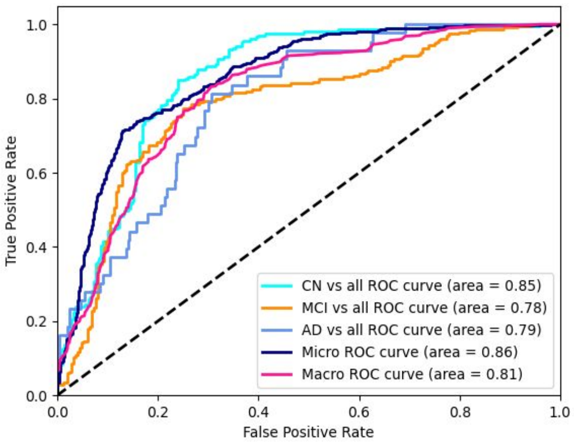
	Full cohort Age>65 (% of n=4945)	**Age>65 with Dementia (all subtypes) (% of n=3187)**
Age mean (standard deviation)	80.19 (7.60)	80.79 (7.43)
Gender: Female	2663(53.85%)	1728(54.22%)
Race: Asian	166(3.36%)	92(2.89%)
Race: Black	311(6.29%)	173(5.43%)
Race: White	3469(70.15%)	2192(68.78%)

Reminder:
ADNI 92% White
NACC 83% White

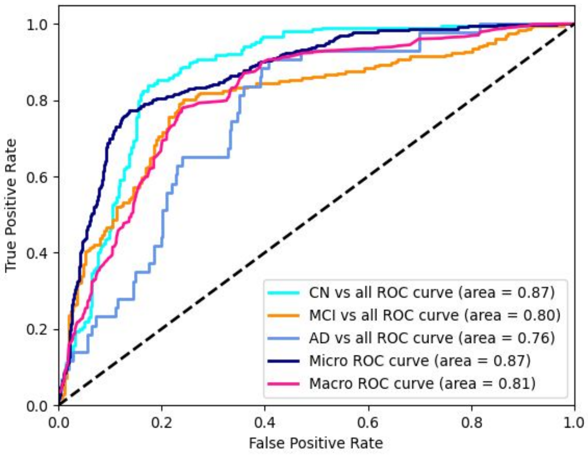
Evaluating our previous model on T1 MRIs



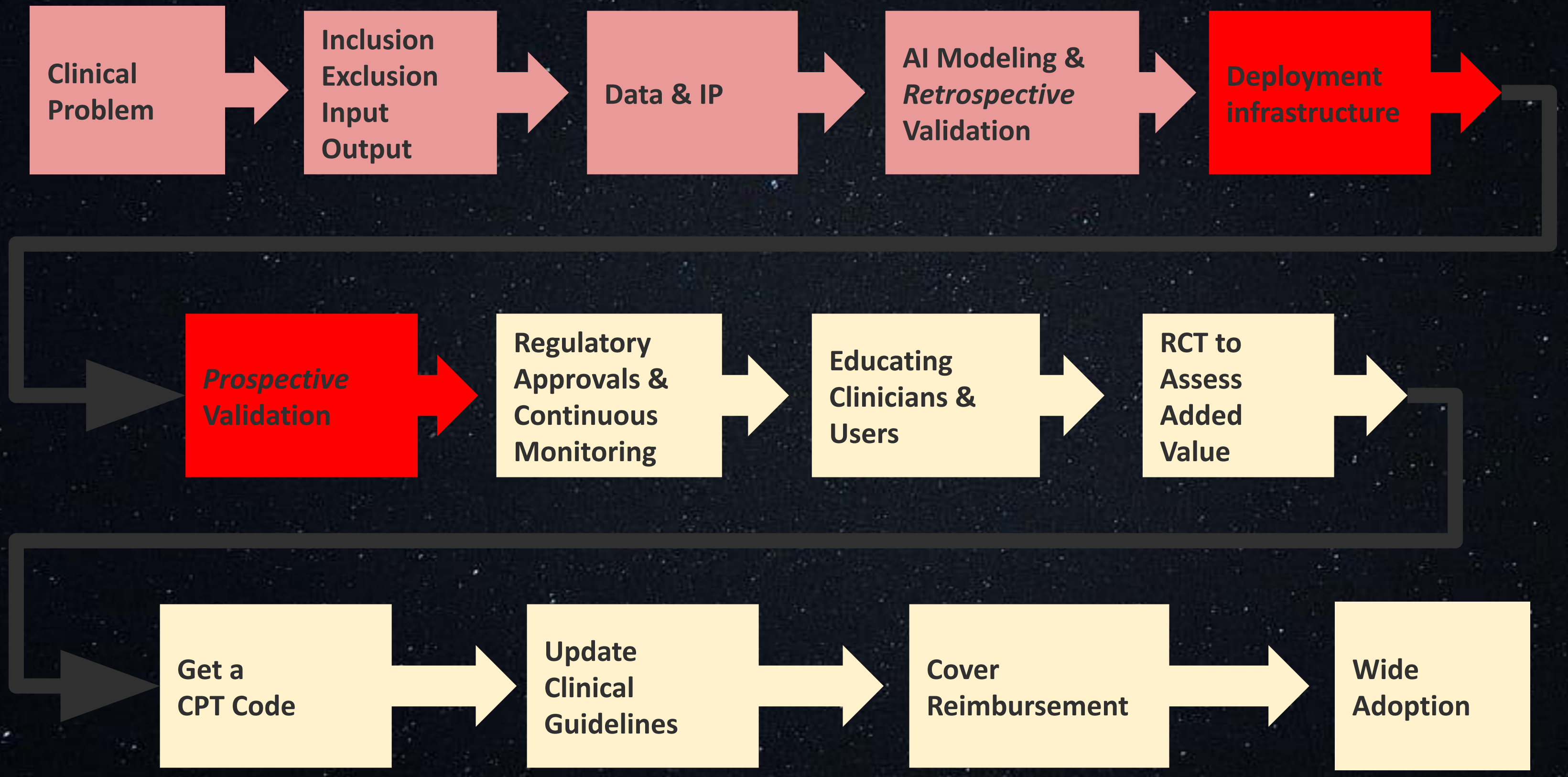
Direct evaluation without re-training



Only fine-tuning the last MLP layers



Re-training the full network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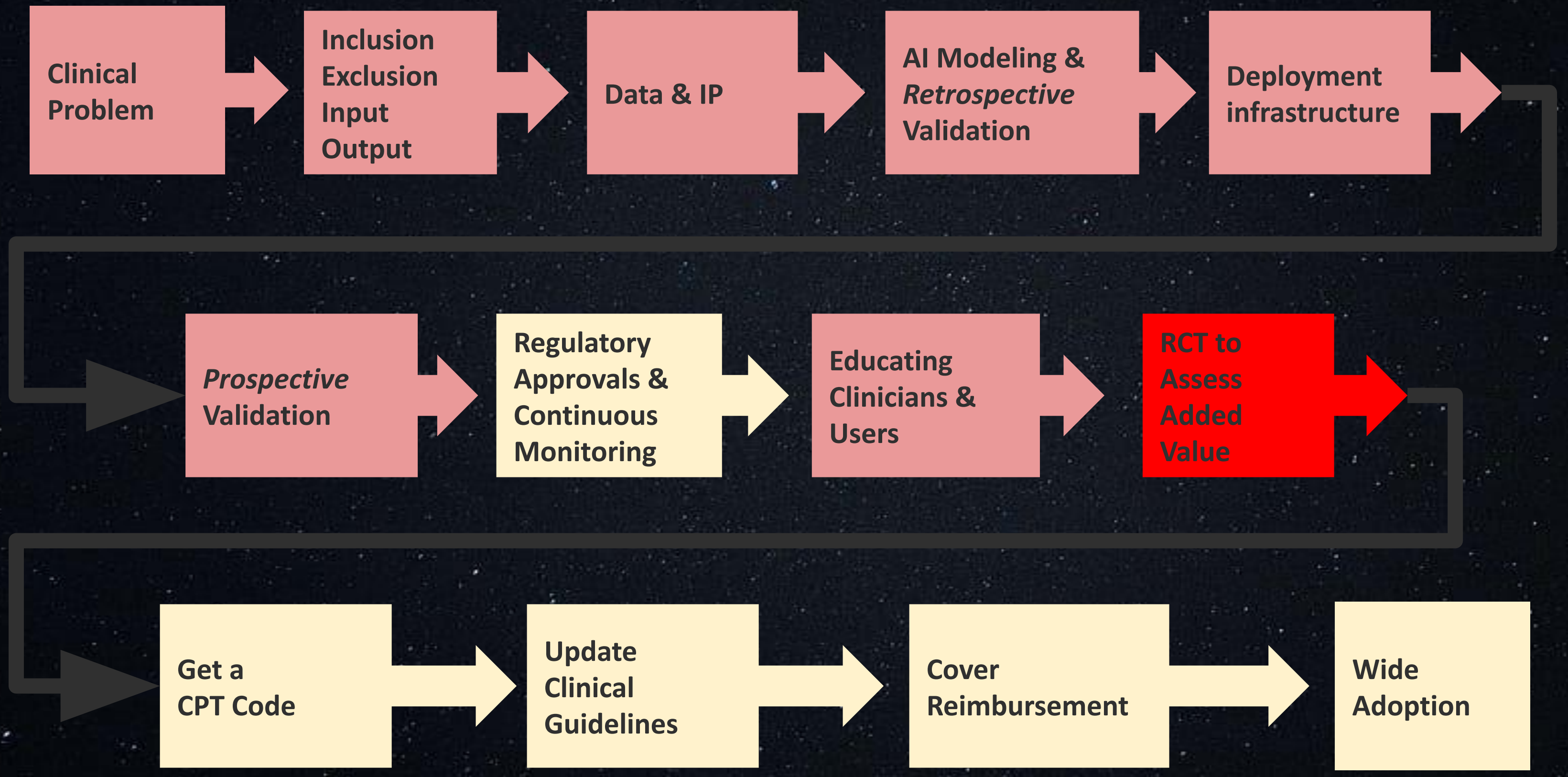
Prospective validation workflow

On a daily basis at 7am, identify Accession ID (Image id) of structural MRIs captured at NYU Langone.

Score with the model and track (MCI+AD) group

Push a PDF back in PACS with scores & explanations

Review by neuro-radiologist residents & measure PPV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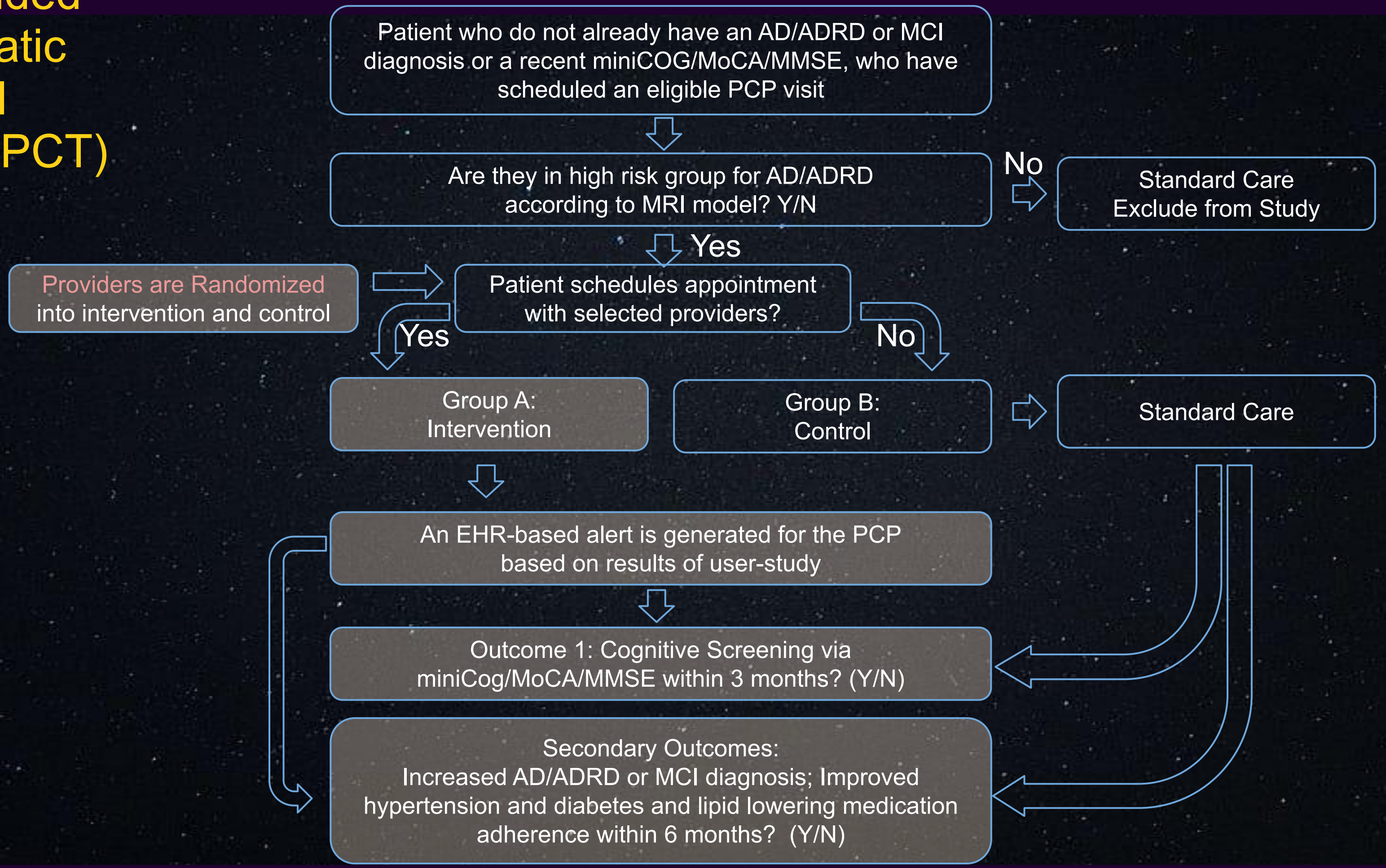
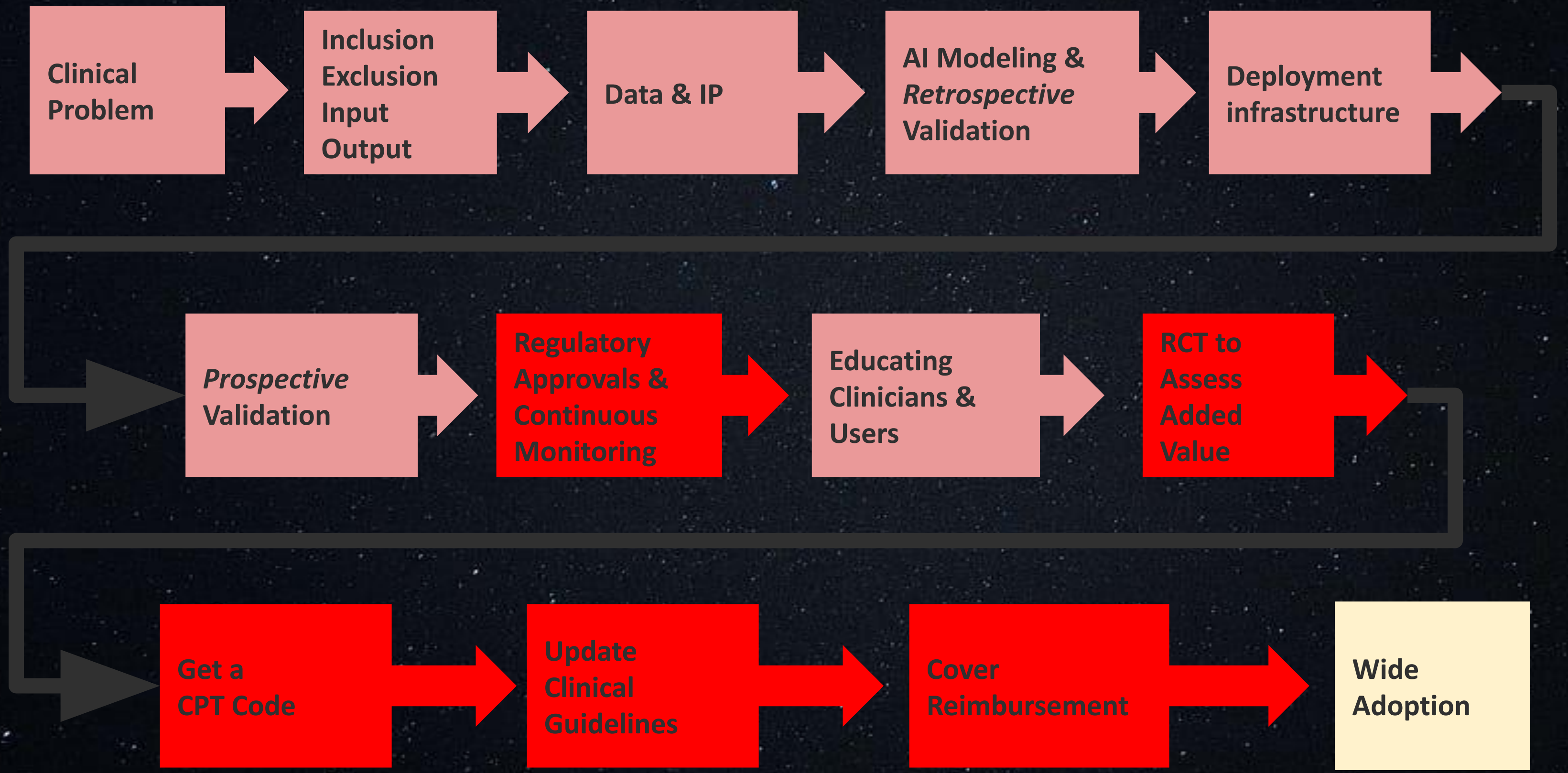
Embedded Pragmatic Clinical Trial (ePCT)

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Take-home messages

Full Implementation of AI in Clinic and achieving clinical impact goes beyond retrospective modeling

Interdisciplinary (Clinical, AI, IT, Vendor, Statistics), and requires support from high-level executives/leadership

Many human factors involved in the pathway from model to clinical impact

It is doable!

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