



AI-Enabled Tumor Assessment Tools

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AI-Enabled Tools Hold Promise to Improve Tumor Assessments

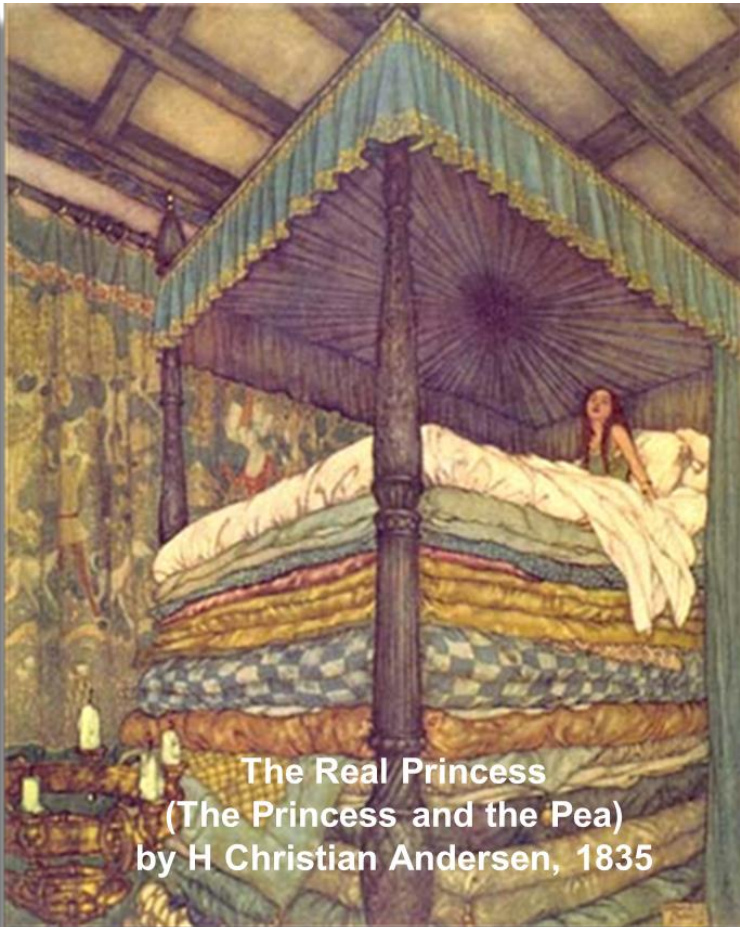
Our multi-stakeholder working group wrote a white paper evaluating the current landscape of AI-enabled tumor assessment tools and proposing a stepwise roadmap for their integration into clinical trial.

FRIENDS
of CANCER
RESEARCH

Leveraging AI-Enabled Tumor Assessment Tools on Radiological Images to Evaluate Treatment Effect and Support Clinical Trial Endpoints in Solid Tumors

White Paper | 2026

RECIST for Assessing Tumor Change Over Time



The Real Princess
(The Princess and the Pea)
by H Christian Andersen, 1835

Cancer An International Interdisciplinary
Journal of the American Cancer Society

The effect of measuring error on the results of therapeutic trials in advanced cancer

Charles G. Moertel MD, James A. Hanley PhD

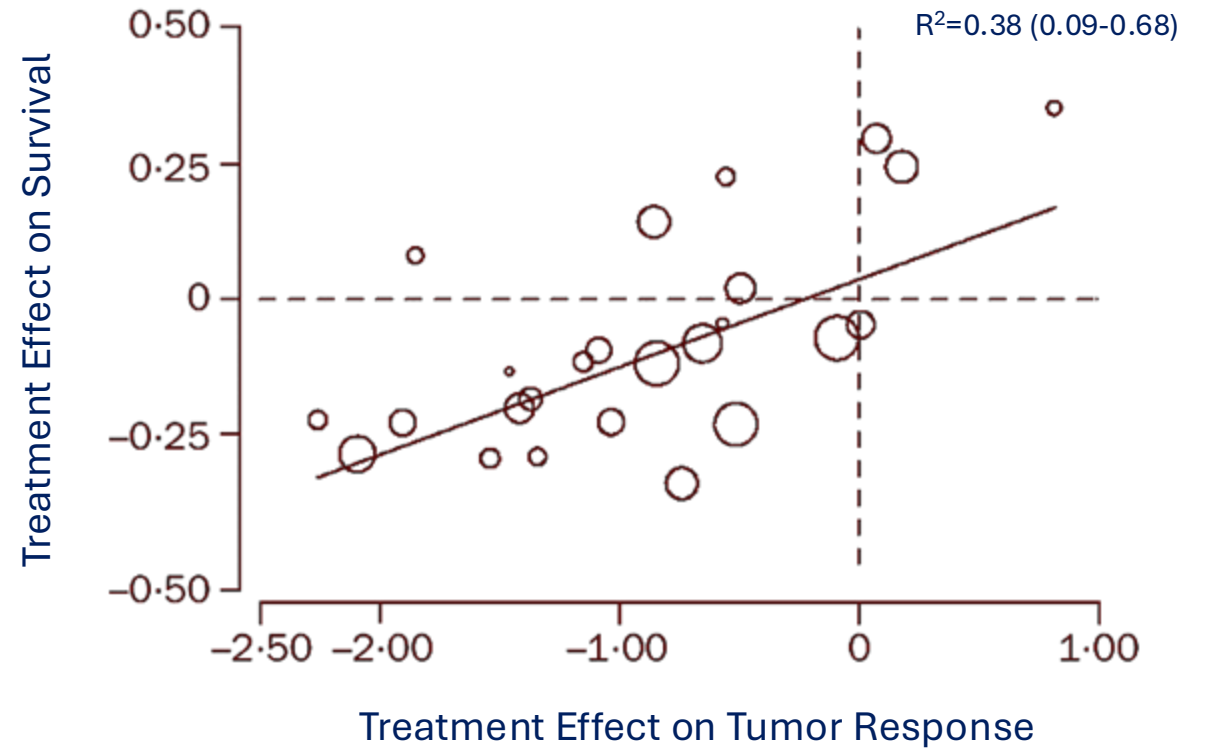
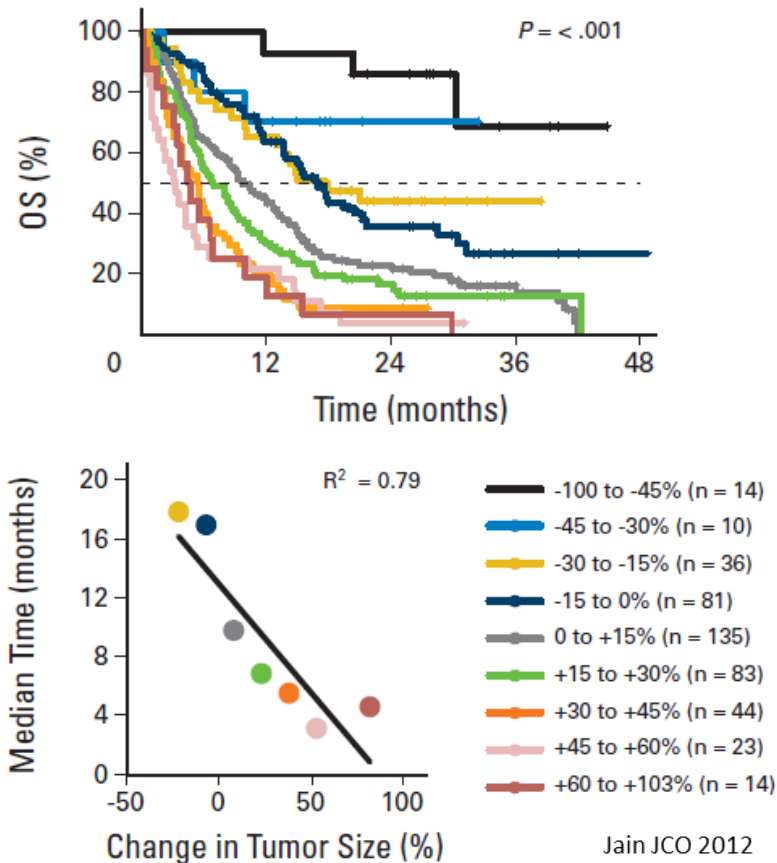
First published: July 1976 |

- 16 oncologists each measured 12 simulated tumor masses placed underneath a mattress
- Two pairs of these tumors were identical in size
- Only with a difference in size of 50% (30% unidimensional) could the simulated tumors be differentiated

RECIST for Assessing Tumor Change Over Time

Greater magnitude of response is associated with a better prognosis for an individual patient

Correlation between tumor response and survival is weaker
Lacking: Reliability, Biological Relevance, Comparative Metrics



RECIST for Assessing Tumor Change Over Time

- Established as a unified approach to simplify and standardize tumor measurement
- Used to define endpoints such as objective response rate (ORR) and progression-free survival (PFS)
- Has provided value for >30 years

Potential Limitations

Subjectivity in lesion selection may limit consistency in capturing tumor dynamics over time

Unidimensional measurements may not capture treatment effect as well as volumetric assessments

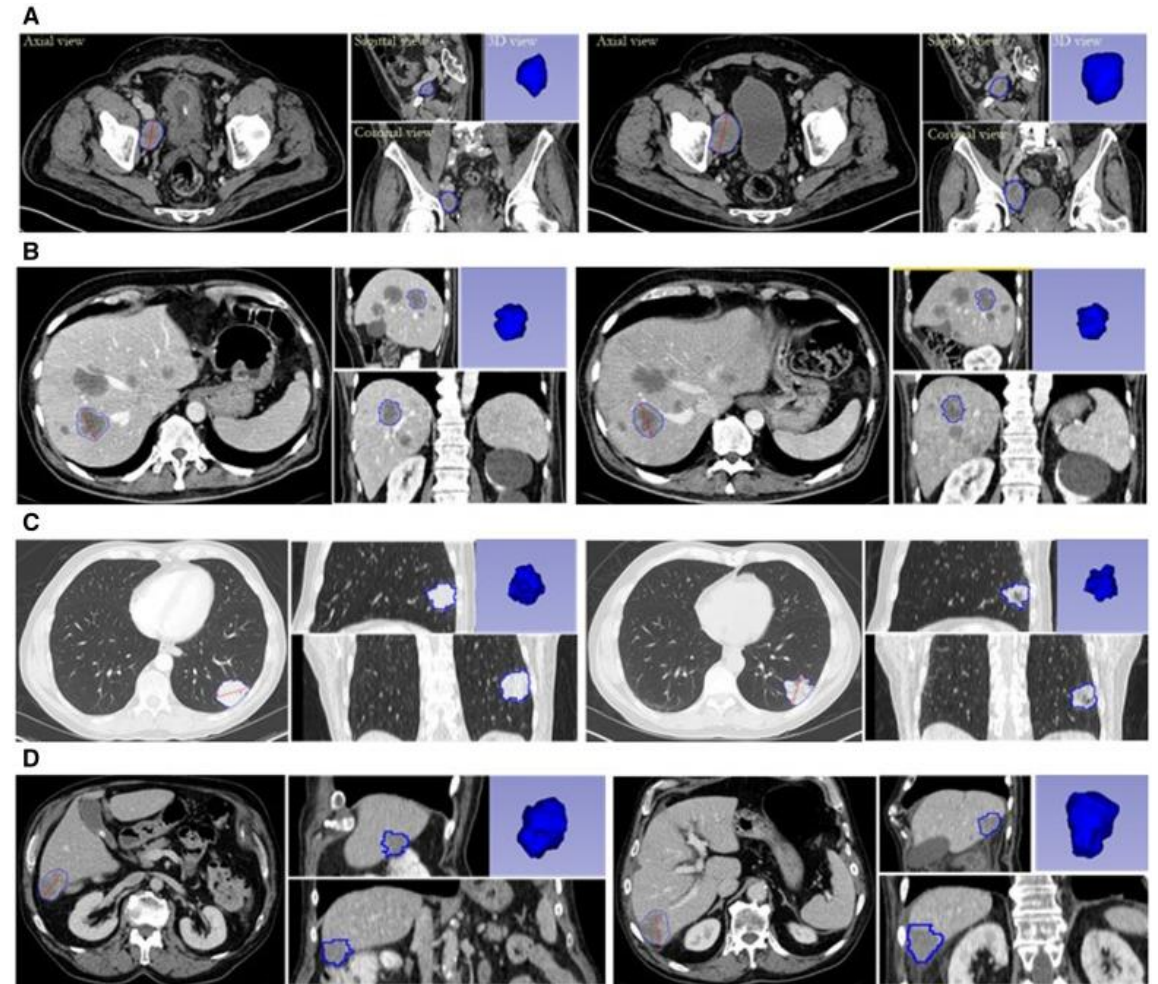
Unable to distinguish between treatment-related changes (i.e., pseudoprogression) and tumor growth

Tracking the 5 largest lesions assumes overall survival (OS) is determined by the behavior of the average lesion

RECIST for Assessing Tumor Change Over Time

- **Immunotherapies** – delayed responses or pseudoprogression
- **Targeted therapies / molecular inhibitors** – stabilize disease or slow growth
- **Antibody–drug conjugates, bispecifics, and cell therapies** – atypical response patterns (mixed responses, deep late responses)

Paradoxically, therapeutic successes—longer survival, crossover, and effective subsequent treatments—have reduced the ability of PFS and ORR to translate reliably into meaningful clinical benefit



AI-Enabled Tumor Assessment Tool Outputs as Novel Endpoints

AI-enhanced RECIST

Radiomics Features

**Volumetric
Assessments**

**Tumor Growth
Kinetics**

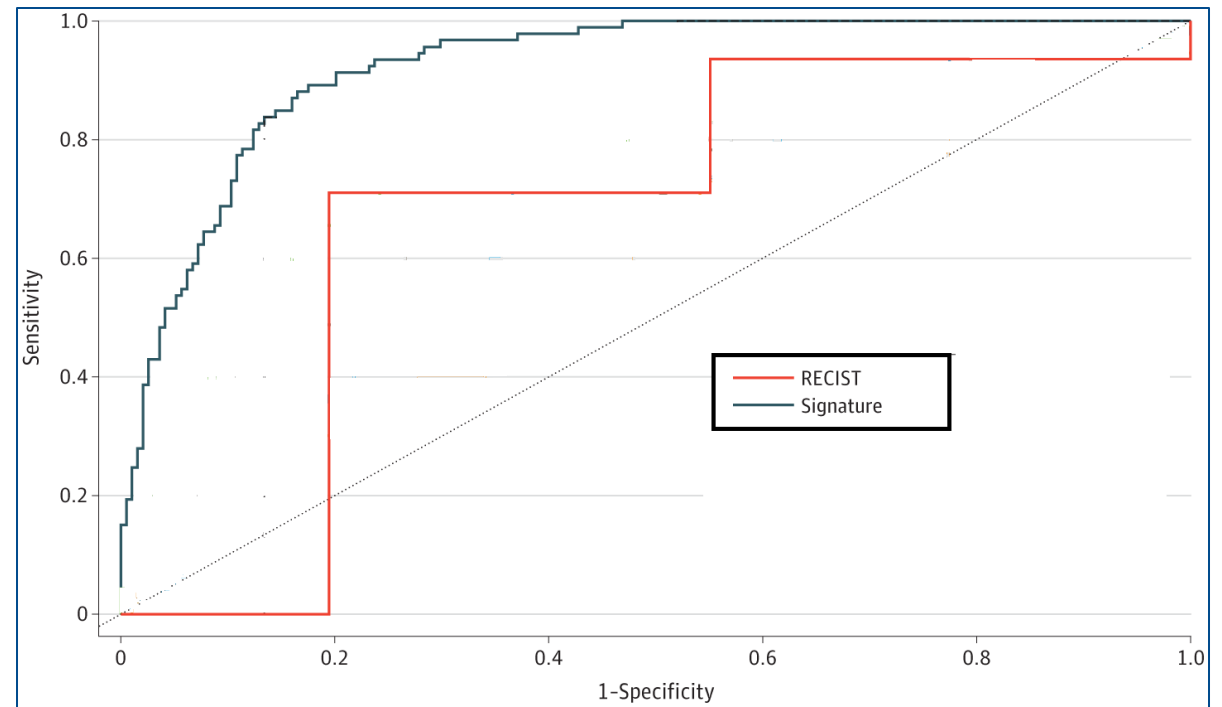
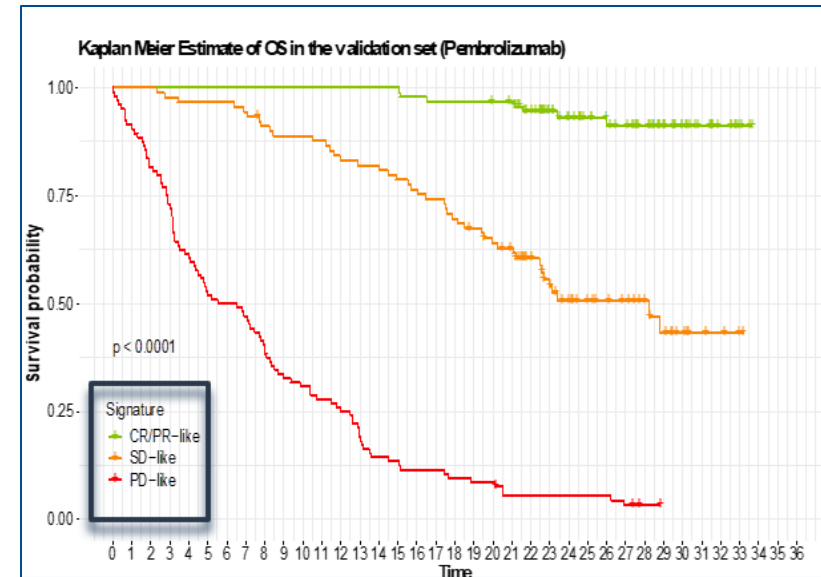
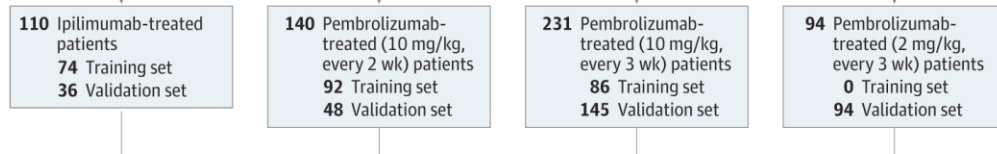
Additionally, consider functional and molecular imaging modalities as well as multi-modal approaches

Radiomics Features

Early Readout on Overall Survival of Patients With Melanoma Treated With Immunotherapy Using a Novel Imaging Analysis

Patients with advanced melanoma

- 1374 Reported in clinical trials
 - 540 KEYNOTE 002
 - 834 KEYNOTE 006
- 1090 Received clinical data by academic core
 - 432 KEYNOTE 002
 - 658 KEYNOTE 006
- 991 Received CT scans by academic core
 - 426 KEYNOTE 002
 - 565 KEYNOTE 006
- 705 Measurable disease at baseline with clinical data
 - 307 KEYNOTE 002
 - 398 KEYNOTE 006
- 668 Measurable disease at baseline and 3 mo with clinical data
 - 285 KEYNOTE 002
 - 383 KEYNOTE 006
- 668 Treated
 - 575 Pembrolizumab, ipilimumab
 - 93 Chemotherapy



Tumor Growth Kinetics

An FDA analysis of the association of tumor growth rate, overall survival and progression-free survival in patients with metastatic NSCLC

Justin N Malinou ✉, Jiaxin Fan, Joyce Cheng, Yutao Gong, Yuan-Li Shen, Erin Larkins

The Oncologist, oyag009, <https://doi.org/10.1093/oncolo/oyag009>

Published: 16 January 2026

Conclusion:

- The g value, as a volumetric measurement of tumor growth rate, may provide an additional or supplementary approach to assess the potential clinical activity of an agent.
- Prospective studies are needed to further assess the association of the g value derived from early tumor measurements with long-term outcomes in patients.

CLINICAL CANCER RESEARCH

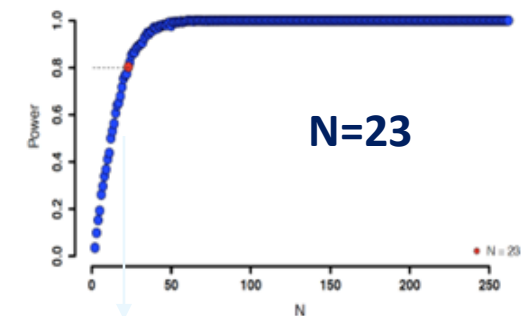
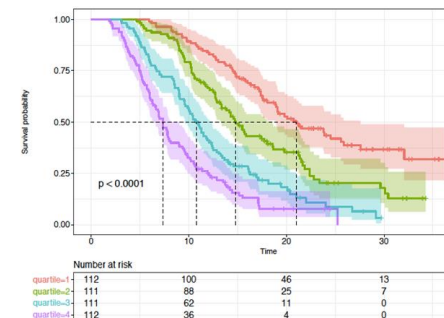
PRECISION MEDICINE AND IMAGING | DECEMBER 15 2020

Enhanced Detection of Treatment Effects on Metastatic Colorectal Cancer with Volumetric CT Measurements for Tumor Burden Growth Rate Evaluation

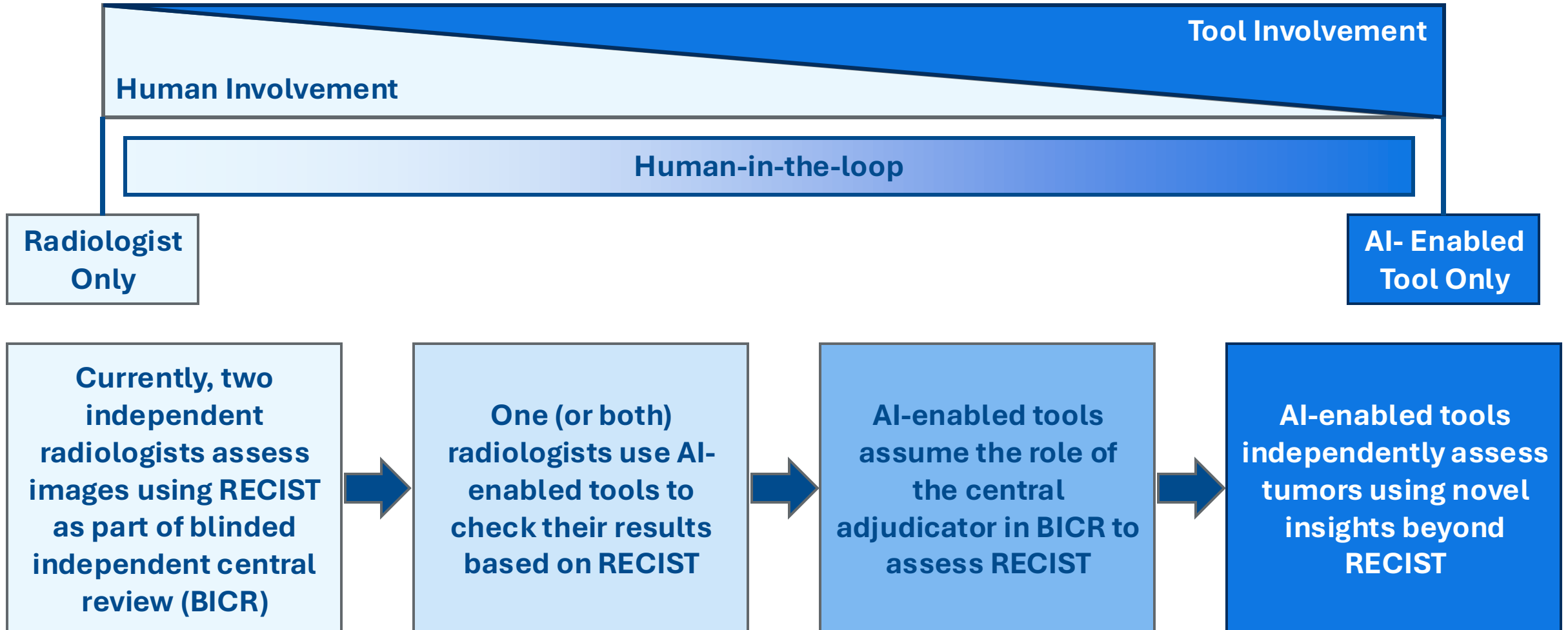
Michael L. Maitland ✉; Julia Wilkerson; Sanja Karovic; Binsheng Zhao; Jessica Flynn; Mengxi Zhou; Patrick Hilden; Firas S. Ahmed; Laurent Dercle; Chaya S. Moskowitz; Ying Tang; Dana E. Connors; Stacey J. Adam; Gary Kelloff; Mithat Gonen; Tito Fojo; Lawrence H. Schwartz; Geoffrey R. Oxnard

Aflibercept Versus Placebo in Combination With Irinotecan and 5-FU in the Treatment of Patients With Metastatic Colorectal Cancer After Failure of an Oxaliplatin Based Regimen (VELOUR)

- Median overall survival 6 WEEK increase
- 1226 patients were prospectively randomized. Retrospective, simulation studies to evaluate number of patients randomized based upon g – with a power of 0.8 was 23

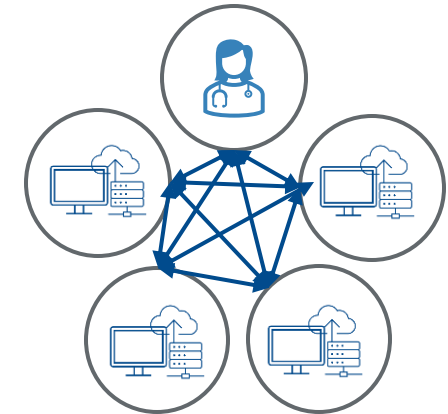
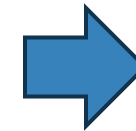
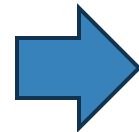
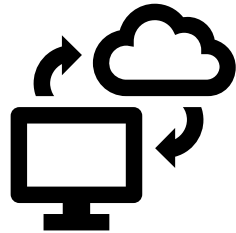


Opportunities for Step-Wise Incorporation of AI-Enabled Tools



AI.RECIST Project

Approach: Assess the variability among AI tools measuring RECIST, as well as with human readers, to establish a baseline understanding and identify opportunities to support best practices.



Develop a common dataset and share with tool developers

Tool developers apply independently developed AI models to assess tumor lesions using RECIST

NCI statisticians compare results with tumor measurements from the clinical trial and among models

Enables a systematic evaluation of variability in RECIST outputs

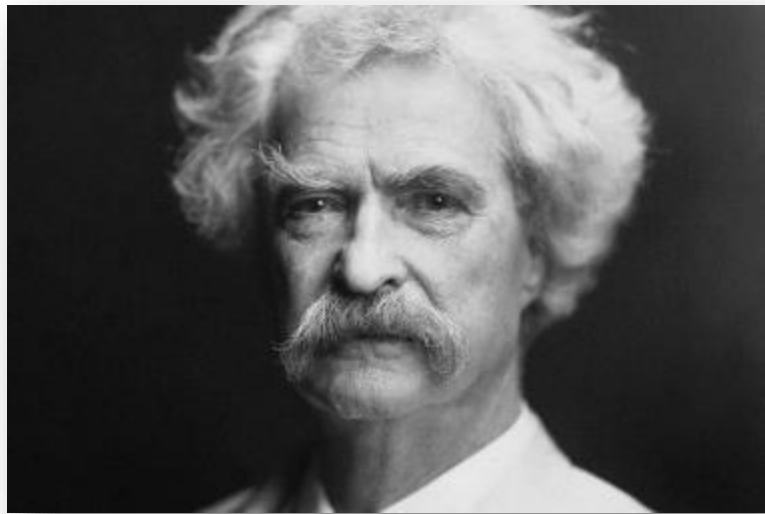
Artificial Intelligence as a Disruptive Technology



“ The role of the radiologist will be obsolete in five years ”

- Vinod Khosla, Founder Sun Microsystems

Friday, April 7, 2017



Radiologist's
∨

The reports of ~~my~~ death have been greatly exaggerated.

~ Mark Twain

2015



**SELF-DRIVING
CARS IN 2 YEARS**

CausalPython.io

2016



**RADIOLOGISTS
OBSOLETE
IN 5 YEARS**

2026



**RADIOLOGISTS
IN REGULAR CARS
DRIVING TO WORK**

Thank you to the project partners!