U.S. FOOD & DRUG ADMINISTRATION

Regulatory Science Challenges for Generative AI Applications in Medical Devices

Digital Health Advisory Committee

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Office of Science and Engineering Laboratories

Center for Devices and Radiological Health

U.S. Food and Drug Administration

Regulatory science for accelerating patient access to innovative, safe and effective medical devices

Office of Science and Engineering Labs (OSEL/CDRH/FDA)

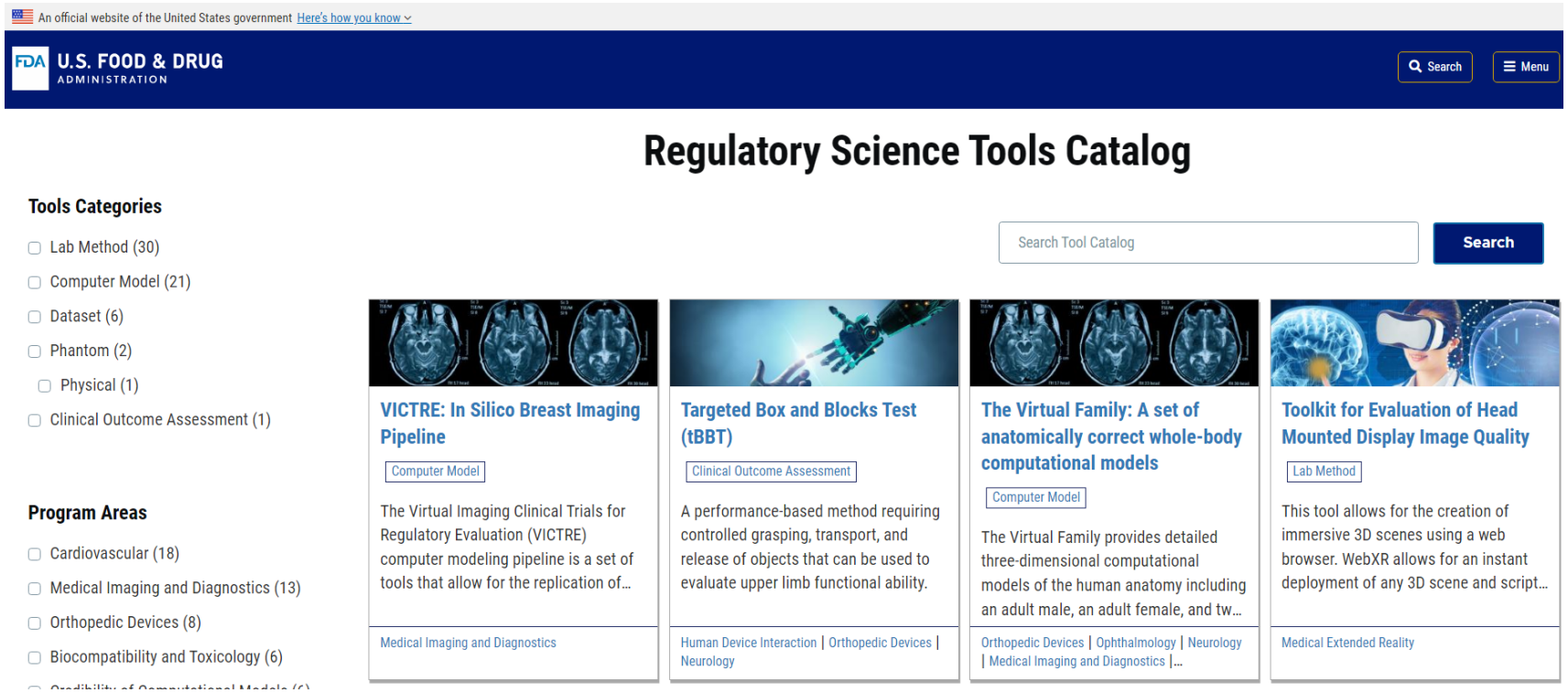
Dedicated to promoting innovation for the development of new lifesaving medical devices

OSEL is organized into 20 program areas

AI/ML program is one of the largest

OSEL outputs are regulatory science tools (RSTs)

Innovative tools for assessing safety or effectiveness of emerging technology that innovators can readily (and voluntarily) incorporate into all stages of device development

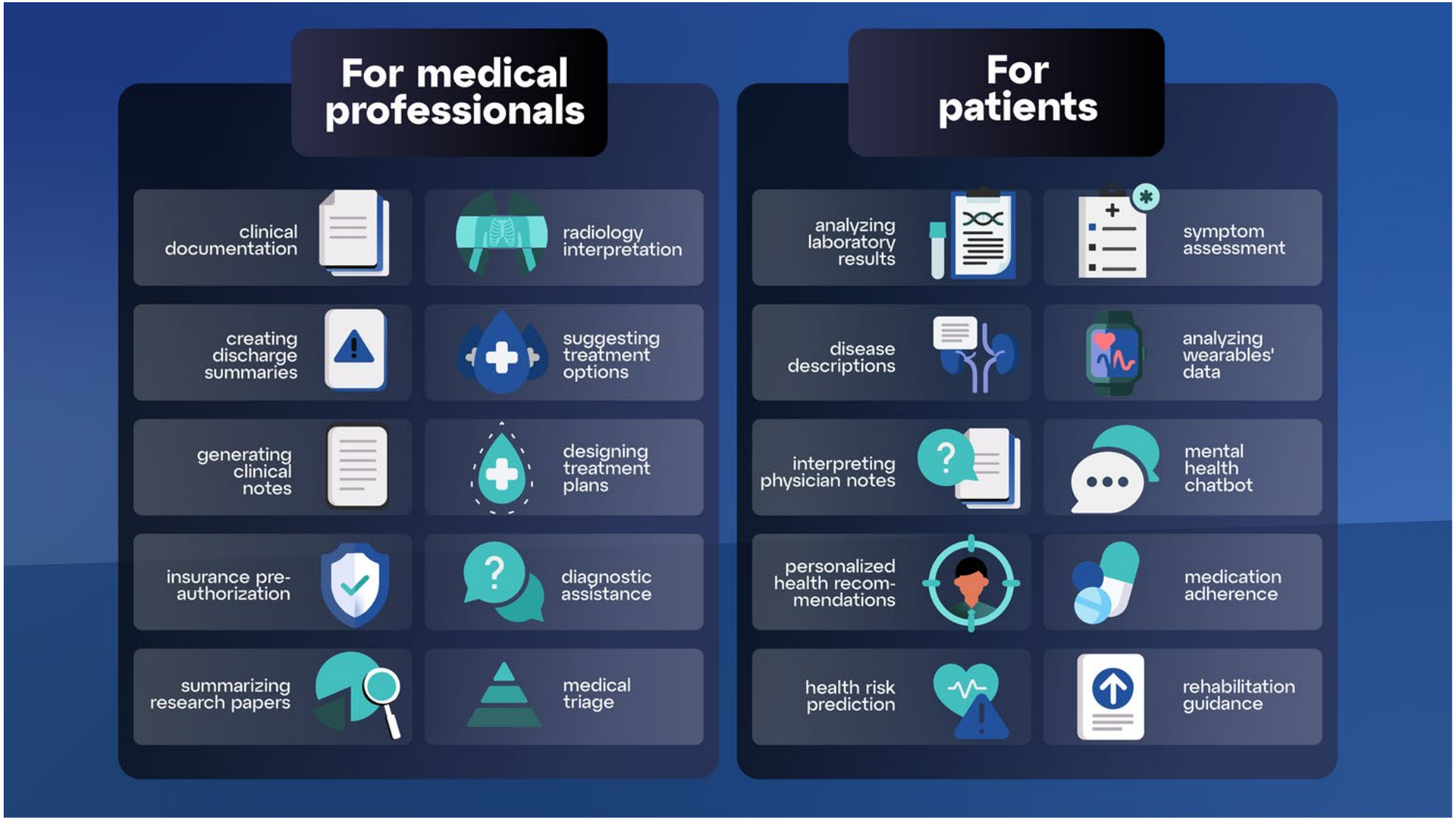


Contact at OSEL_CDRH@fda.hhs.gov

RST Catalog: https://cdrh-rst.fda.gov/

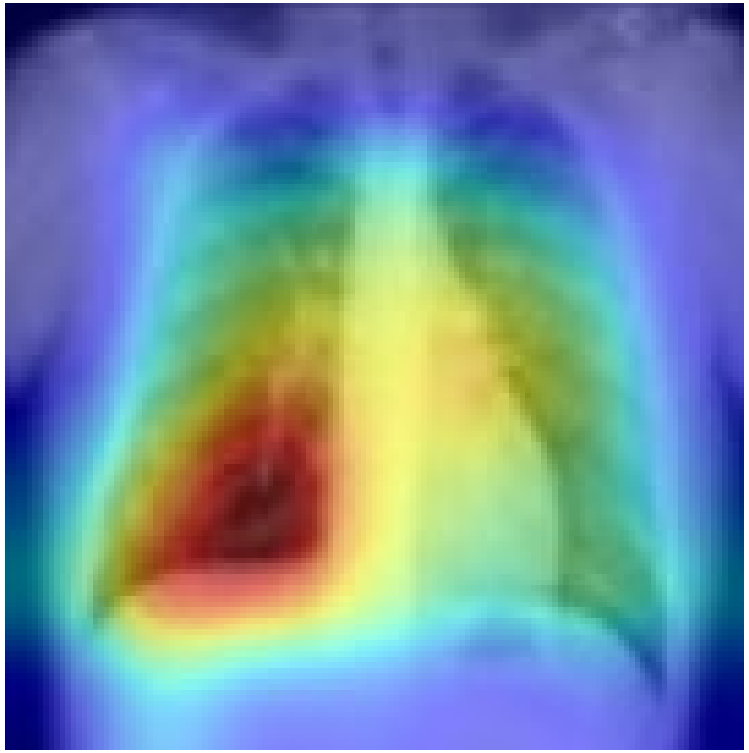
www.fda.gov/about-fda/cdrh-offices/office-science-and-engineering-laboratories

Generative AI in Healthcare



Meskó, B., Topol, E.J. The imperative for regulatory oversight of LLMs (or generative AI) language models in healthcare. *npj Digit. Med.* 6, 120 (2023)

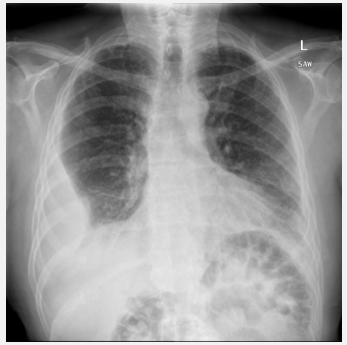
Regulatory Science Challenges for GenAI-Enabled Medical Devices



- Difficulty in defining scope of product's intended use, e.g., due to open-ended inputs and outputs
- Foundation models not under the provenance of medical device manufacturer
- Providing oversight for an adaptive system
- Identification of hallucinations
- Adequacy of data sets for testing, including diversity
- Evaluation of and monitoring for performance in the real world, including bias
- Providing transparency to users

Example Use Case of Generative AI in Radiology

Inputs



Prompt: Generate a radiology report for the provided chest x-ray

Gen Ai Device

Clinician

Output

Device-generated report
…

Clinician-generated report

Indication: recent onset increased SOB

Impression: Unchanged loculated right pleural fusion. No change chronic interstitial lung disease

Source: Indiana University Chest X-ray Collection | Open-i

No changes were made.

Performance Assessment Strategies for GenAI in Healthcare

Benchmarking

with standardized reference datasets

Expert evaluation

including holistic evaluation of AI-human interactions

Model-based evaluation

including automated testing

Performance Assessment Strategies: **BENCHMARKING**

What is it?

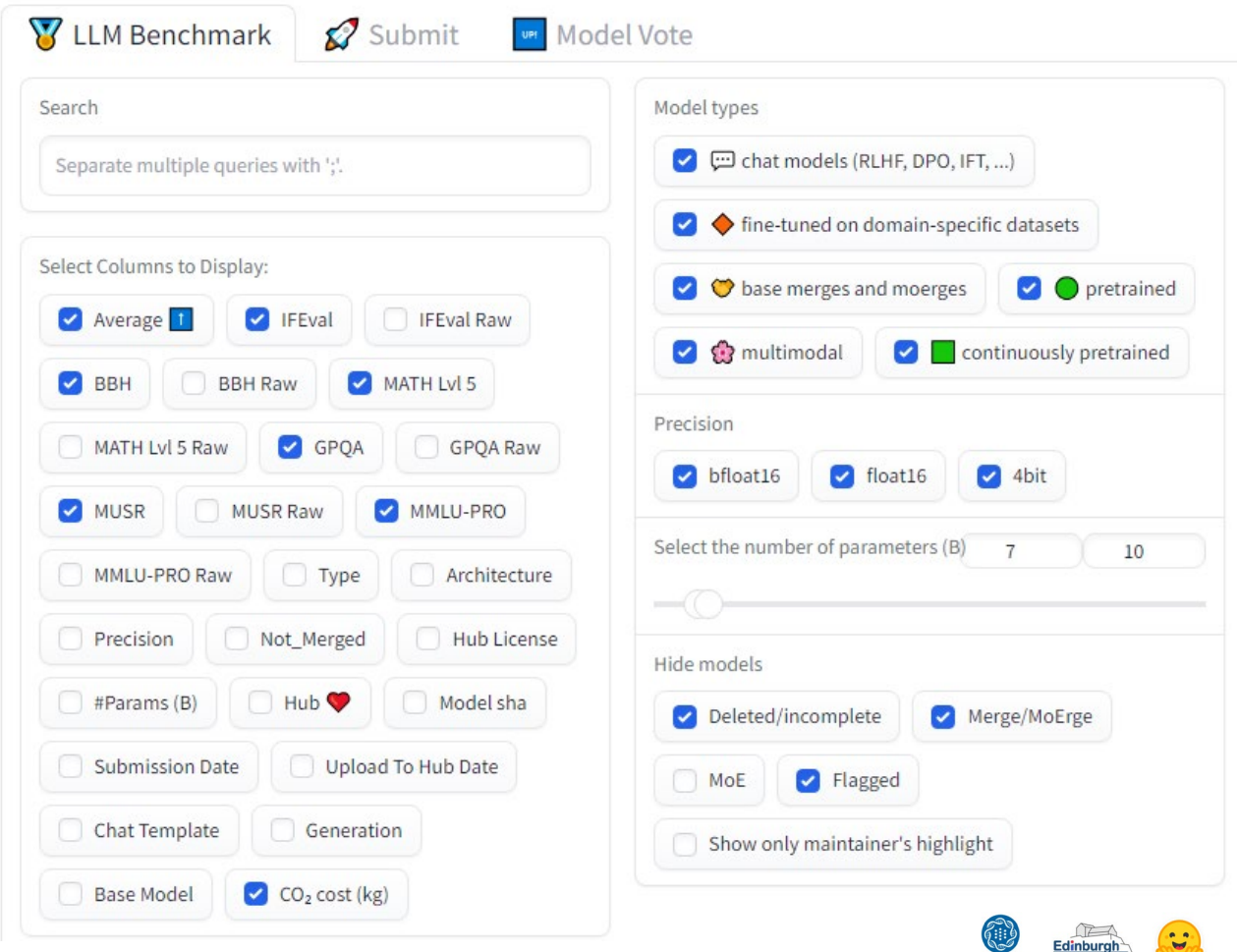
Evaluating models on specific tasks using external test datasets and predetermined metrics.

Advantages

- Practical and available
- Allows head-to-head comparisons
- Large scale

Disadvantages

- Limited in tasks and datasets
- Train-to-the-test overfitting



Performance Assessment Strategies: **EXPERT EVALUATION**

What is it?

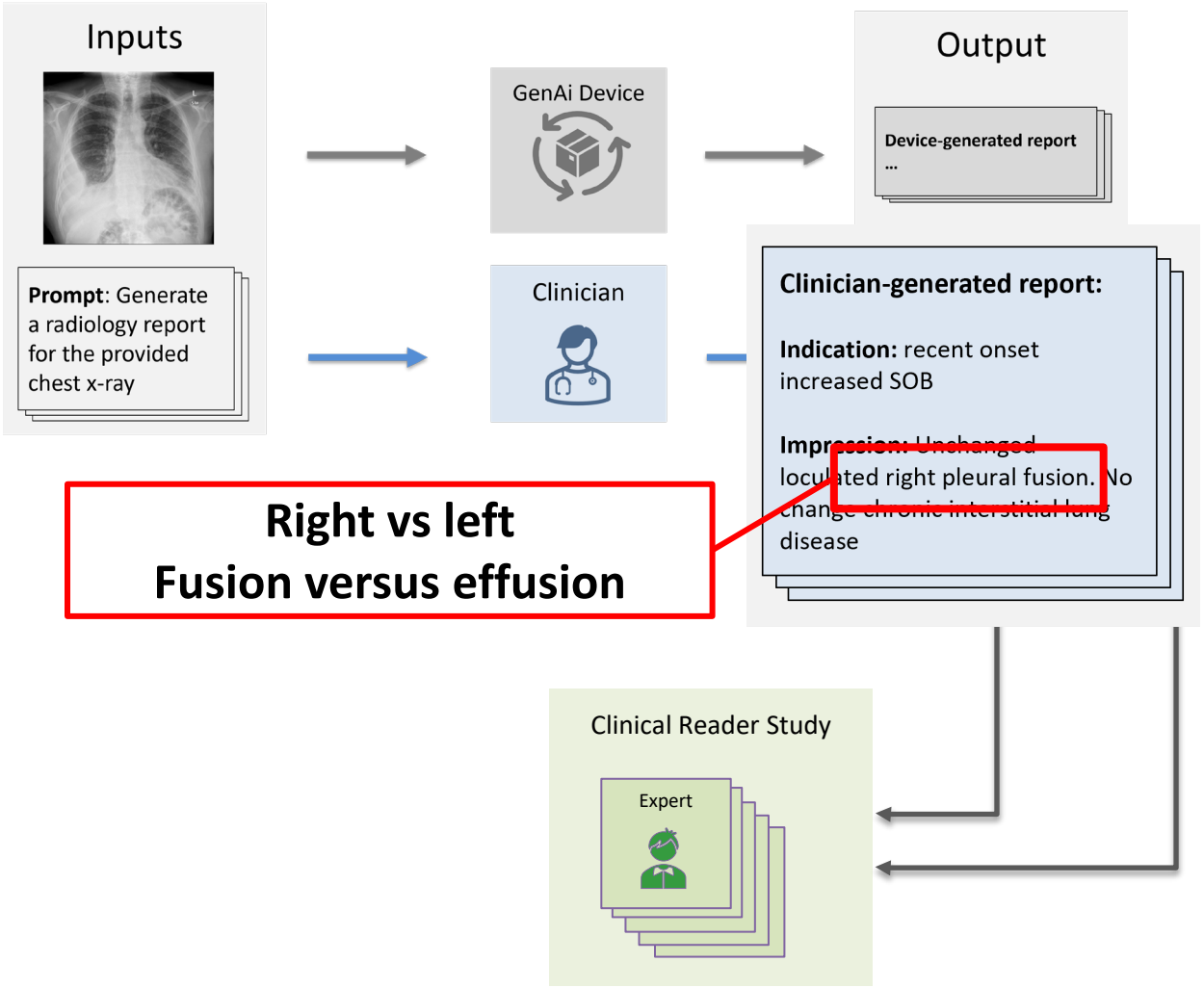
Evaluating models using expert annotations as the reference standard.

Advantages

- Adaptable to new medical tasks
- Direct clinical relevancy

Disadvantages

- Resource intensive
- Subjective and highly variable



Performance Assessment Strategies: **MODEL-BASED EVALUATION**

What is it?

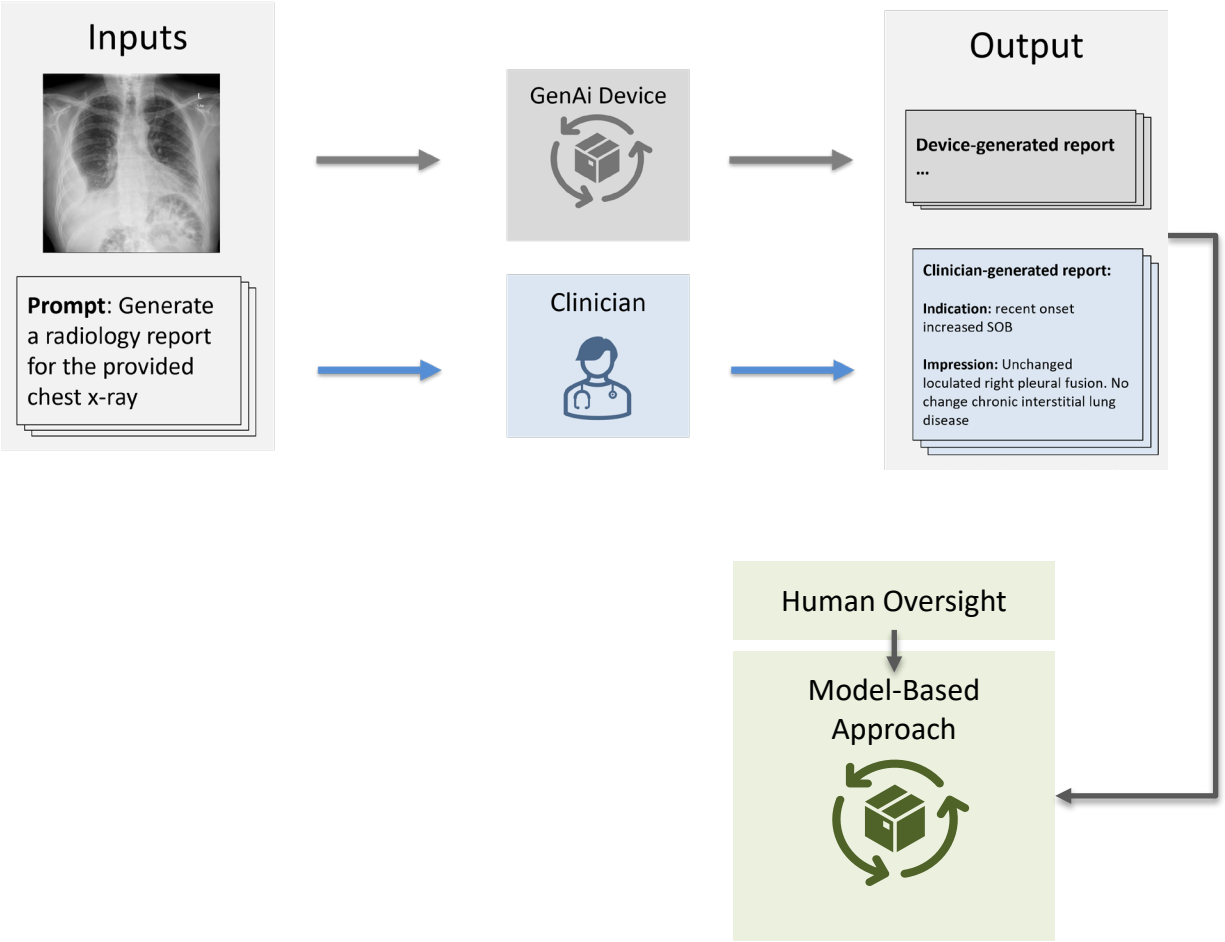
Evaluating models using a *model-based approach* (may be based on genAI) with human oversight

Advantages

- Augments human evaluation
- Scalable

Disadvantages

- Burdensome validation
- Inter-model leakage



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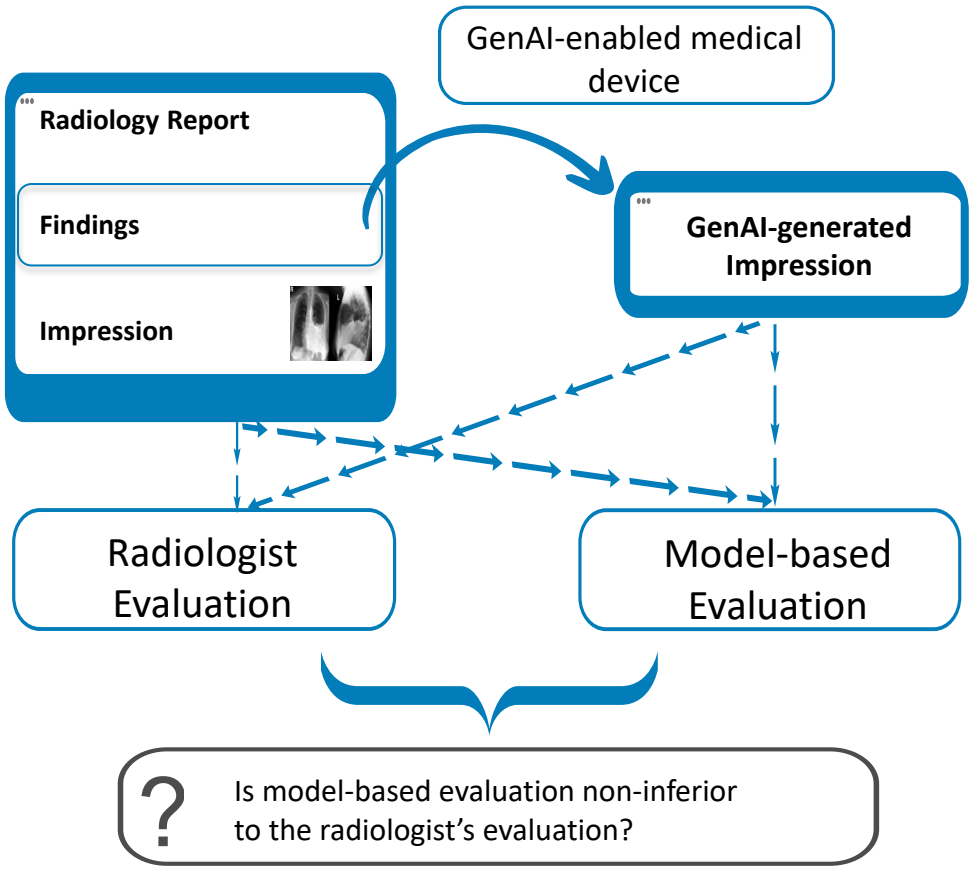

Current research in OSEL aims at developing a case-agnostic approach to characterizing factual accuracy: e.g., are the findings in the genAI-generated report found in the reference report?

Summary

For some GenAI, known evaluation strategies may apply

For some GenAI, new evaluation methodologies and new performance metrics may need to be developed

Performance evaluation requirements are governed by the intended use and associated risk

Totality of evidence may include pre- and post-market elements

Thank you for your attention

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