Foundation Models for Medical Devices

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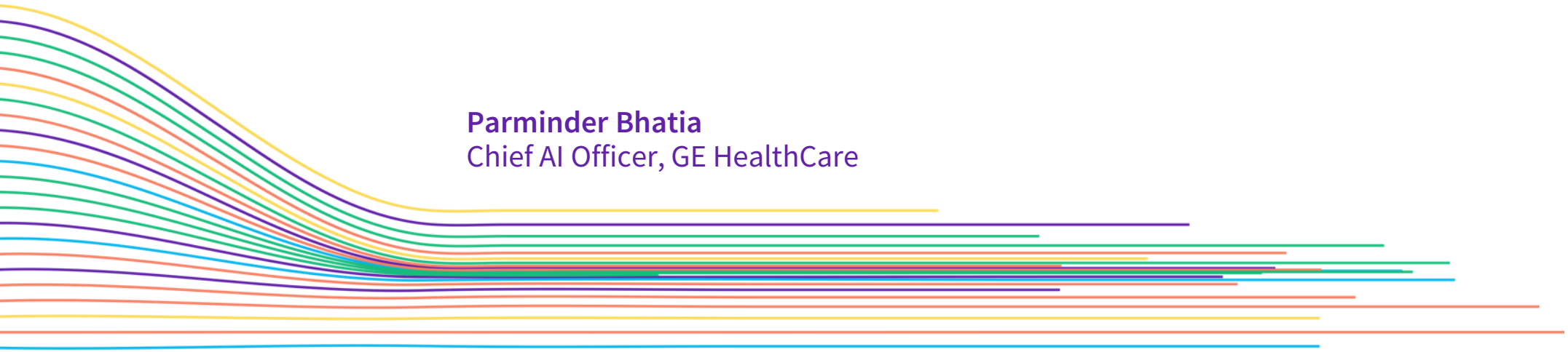

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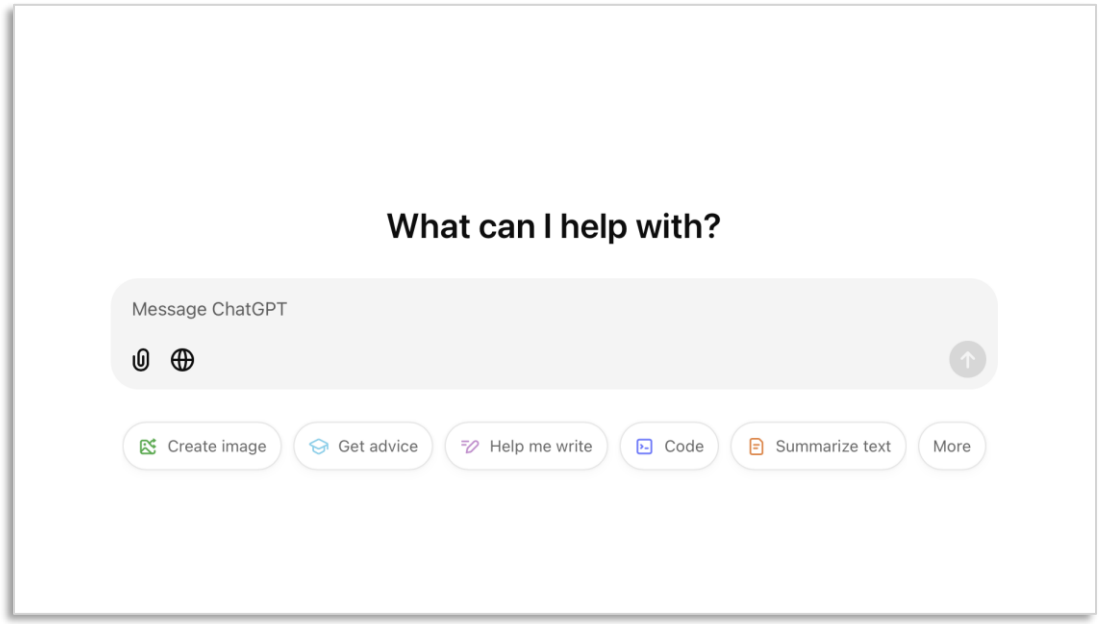
Agenda

- Generative AI and foundation models
- How foundation models can transform healthcare
- Considerations for generative AI-enabled medical devices

ChatGPT: components



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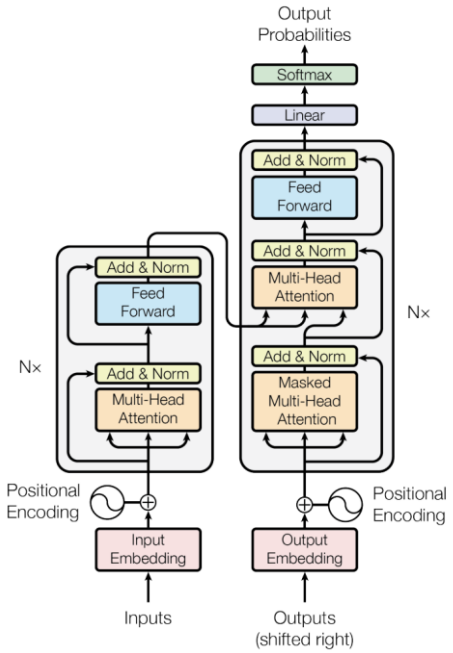

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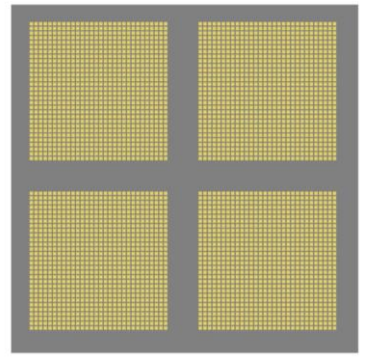

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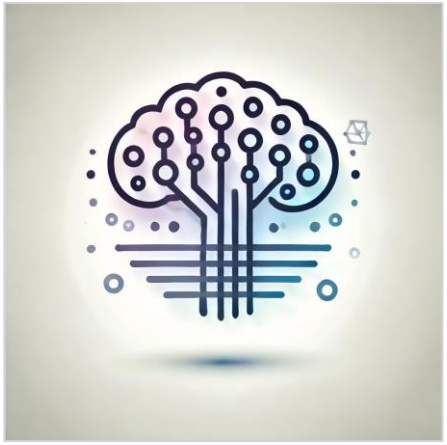


12 Jun 2017 : Attention is all you need: Ashish Vaswani, Noam Shazeer, Niki Parmar, Jakob Uszkoreit, Llion Jones, Aidan N. Gomez, Lukasz Kaiser, Illia Polosukhin

Foundation models: advanced AI built to tackle a multitude of tasks

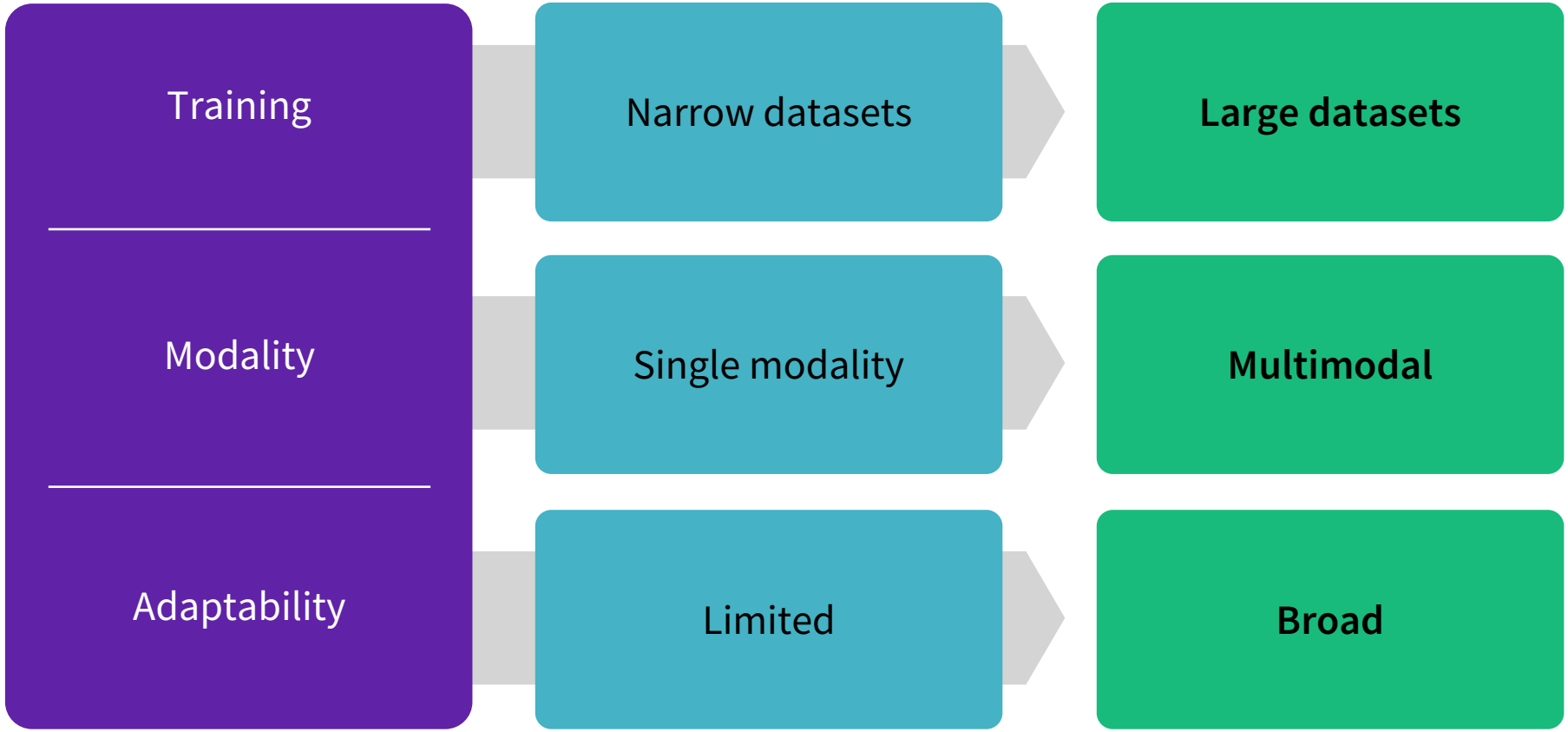
Models trained on a large amount of generalized and unlabeled data

Chat GPT, BERT, Claude, GE HealthCare research models for X-Ray and MRI, etc.

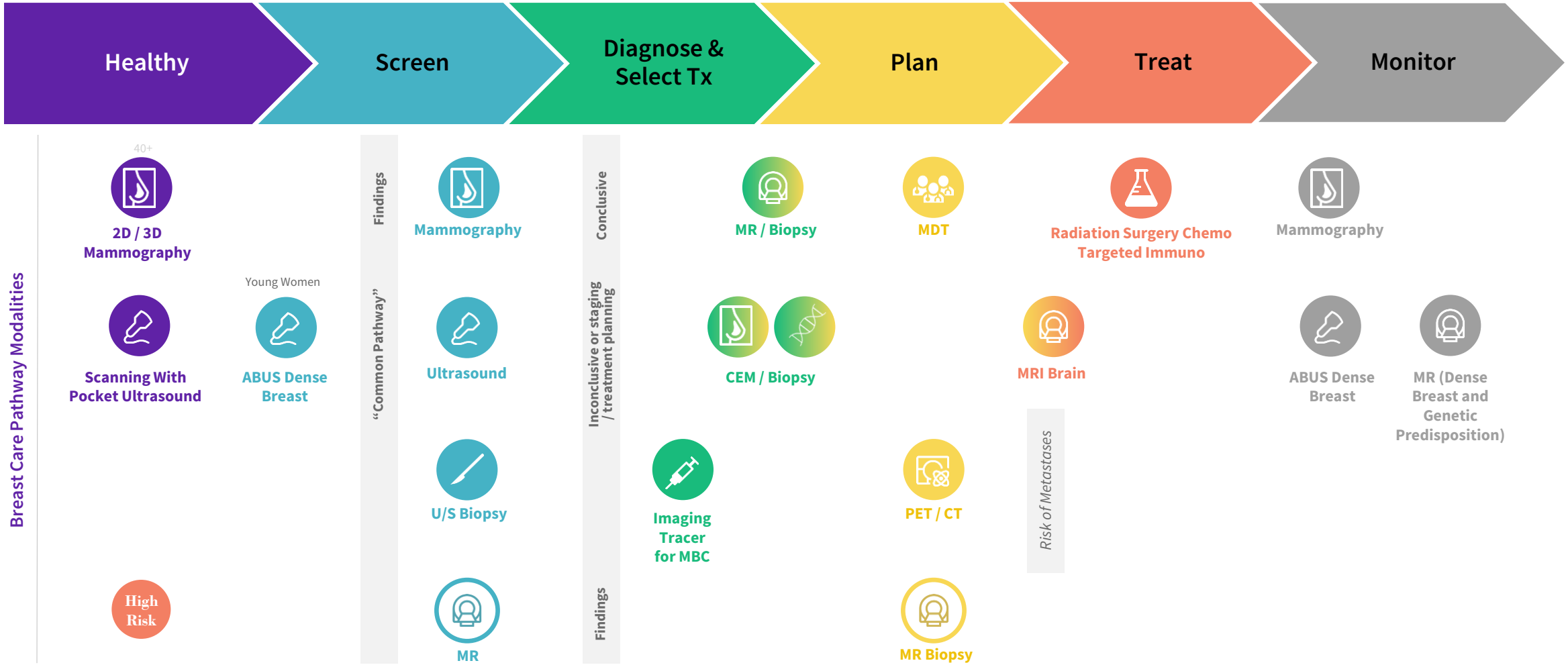
Can be fined tuned for a diverse range of data and tasks

Text, images, diverse inputs, diverse modalities, diverse tasks etc.

A leap forward for AI in healthcare

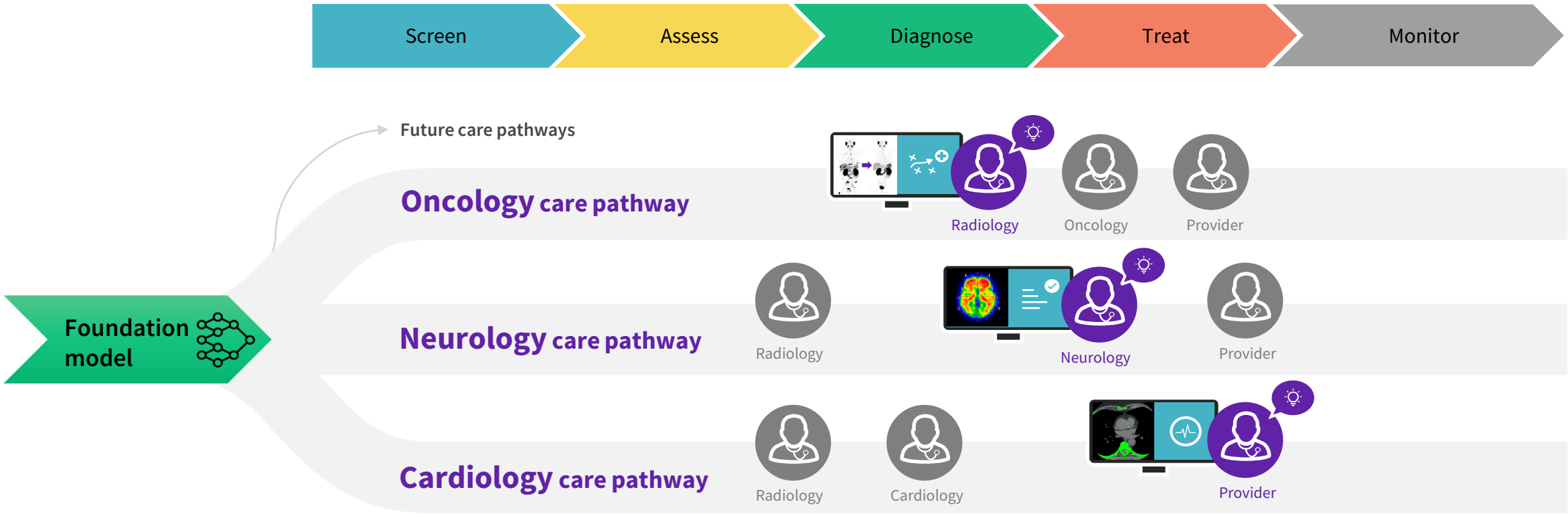


Oncology: Breast cancer pathway



Leveraging foundation models to streamline disease based clinical workflows to address key customer challenges

Foundation models bridge gaps between data silos

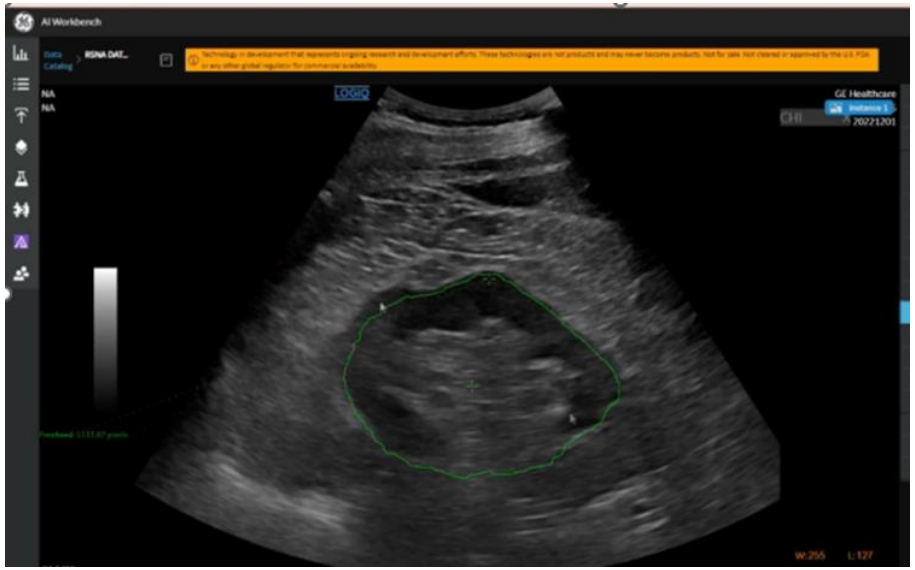


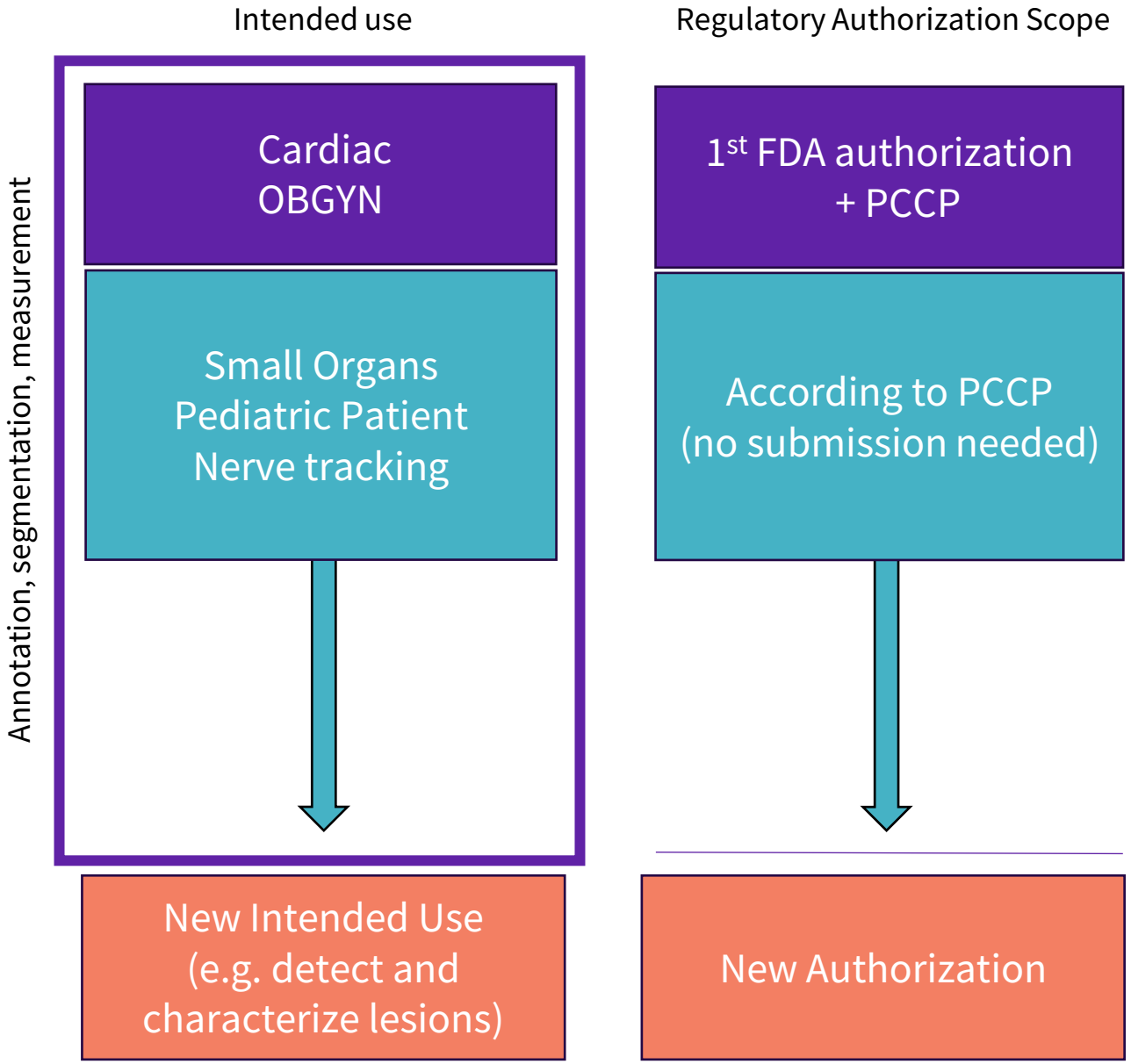
Considerations for generative AI-enabled devices

- Define intended use
- Adopt robust risk management methods
- Conduct performance assessment
- Establish change control & lifecycle management

Define the intended use

SonoSAM:
Interactive Image Analyzer for Ultrasound





PCCP: Pre-Determined Change Control Plan

Adopt a robust risk management process

Adopt a robust risk management process

Hallucinations	Ontology-based model and machine reasoning
Misrepresentation of clinical information	Explainability and transparency
Contaminated or biased data	Source data bias and fairness audits
Data/concept drift	Temperature control for repeatable results
Overreliance on output	Human in the loop

Example of mitigations

Example: System intended for Medical Diagnoses or Treatment Recommendation

Hazard: Underdiagnosis of Rare or Atypical Conditions

Scenario: An AI model trained predominantly on common diseases and typical patient presentations might fail to recognize rare conditions.

For example, a patient with rare autoimmune disease symptoms could be misdiagnosed with a more common condition, such as rheumatoid arthritis, because the AI lacks exposure to the rare disease in its training data.

Example of Mitigation Plan

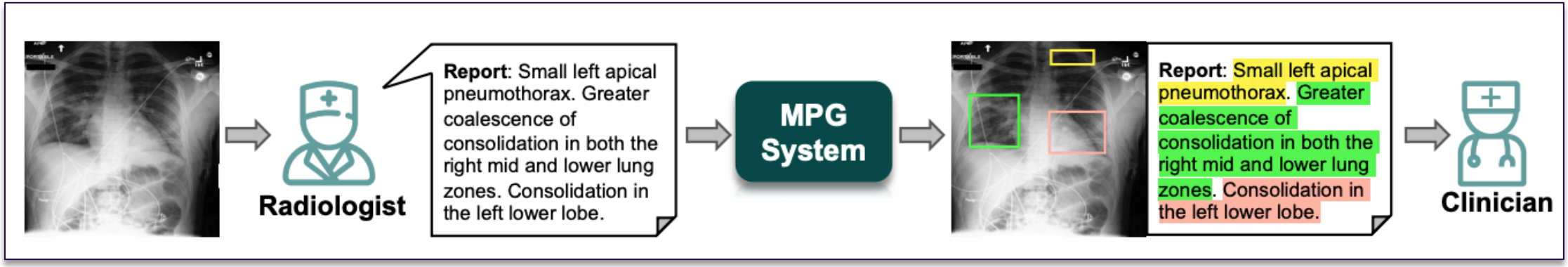
- **Machine Reasoning Algorithm**:
  - Enable machines to mimic human-like reasoning, such as deductive, inductive, or abductive reasoning, and to handle complex tasks like problem-solving, decision-making, and learning
- **Ontology-based disease model**:
  - Provide a structured framework that facilitates the understanding, organization, and sharing of medical knowledge, enabling more efficient diagnosis, treatment, and research

https://pmc.ncbi.nlm.nih.gov/articles/PMC7286047/

Visual grounding

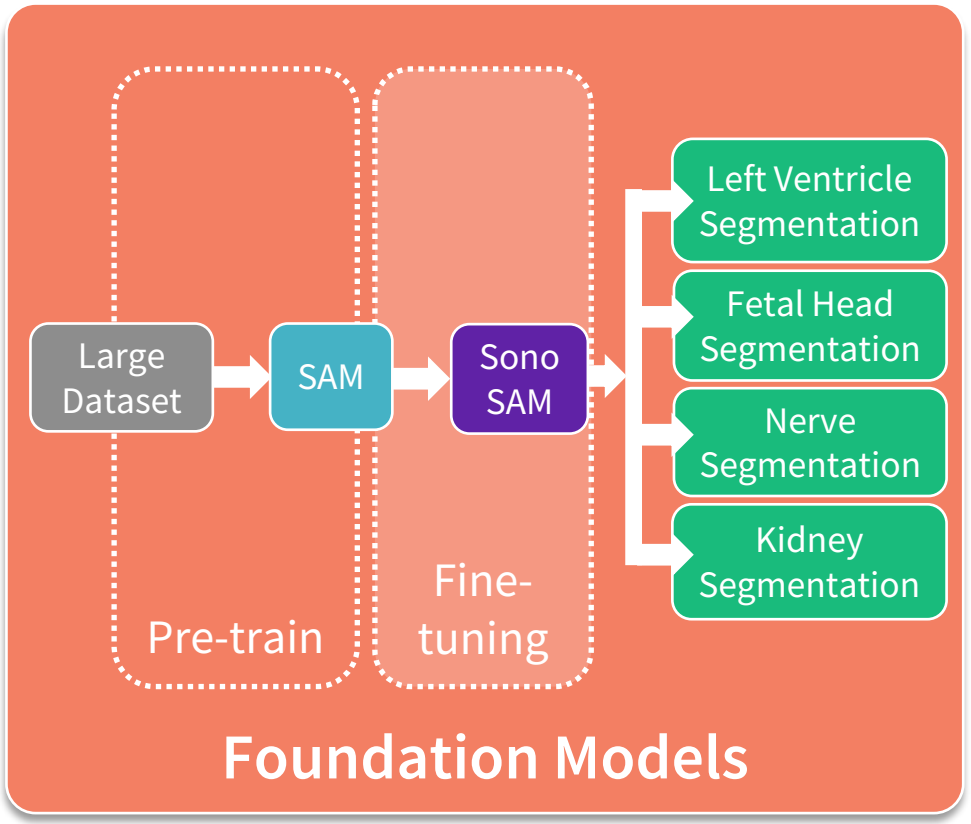
Task: Locate relevant objects on an image based on natural language descriptions

- Better image understanding
- Faithfulness of AI algorithms



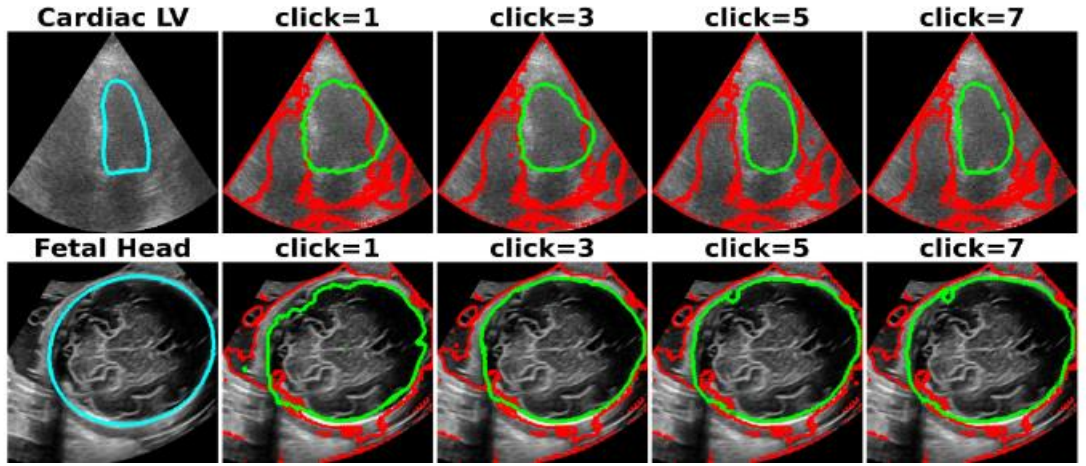
Zou, Ke, et al. "MedRG: Medical Report Grounding with Multi-modal Large Language Model." *arXiv preprint arXiv:2404.06798* (2024).
Chen, Zhihao, et al. "Medical phrase grounding with region-phrase context contrastive alignment." *MICCAI*, 2023.
Bernstein MH, Atalay MK, Dibble EH, et al. Can incorrect artificial intelligence (AI) results impact radiologists, and if so, what can we do about it? A multi-reader pilot study of lung cancer detection with chest radiography. European Radiology 2023;33:8263–9.

Performance assessment: SonoSAM



- Performance on an independent & representative dataset of Ultrasound across 6 anatomical regions

- Compared to SAM*, SonoSAM:
  - Reaches 0.8 DICE with less clicks in 5/6 tested anatomies
  - Reaches 0.9 DICE with less clicks in all tested anatomies



Blue – Ground Truth; **Red** – SAM prediction; **Green** – SonoSAM Prediction

*Segment-anything.com

Ravishankar, H. et al., (2024). SonoSAMTrack: Segment and Track Anything on Ultrasound Images. arXiv. https://doi.org/10.48550/arXiv.2310.16872

Technology in development that represents ongoing research and development efforts. These technologies are not products and may never become products. Not for sale. Any reported results are preliminary and subject to change. Not cleared or approved by the U.S. FDA or any other global regulator for commercial availability.

Gen AI/FM-enabled medical device change control & lifecycle management

Change control

- Maintain version control & end-to-end validation
- Configure model to produce consistent output

Adaptability & speed

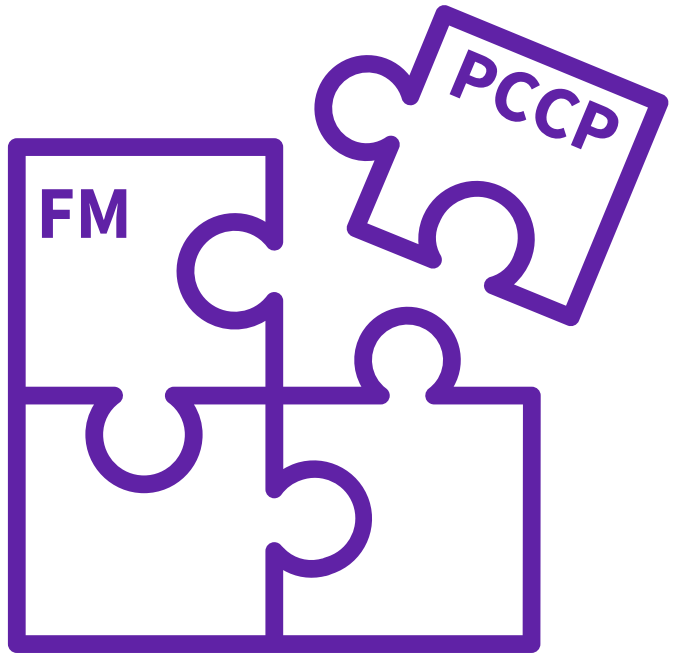
- Leverage PCCP to expand use within intended use
- Build speed to allow quick iterations (e.g. adopt new FM version)

Post-market monitoring

- Evaluate best software practices to capture feedback during use
- If device risk level requires it, consider mechanisms to monitor ongoing performance as a risk mitigation

Conclusion

- Foundation Models (FM) have the potential to transform healthcare
- They can be safely integrated with medical devices with the right controls in place
- We can leverage currently available technological best practices within the existing regulatory framework
- By bringing FM together with a pre-determined control plan, we can achieve timely and safe change management



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