

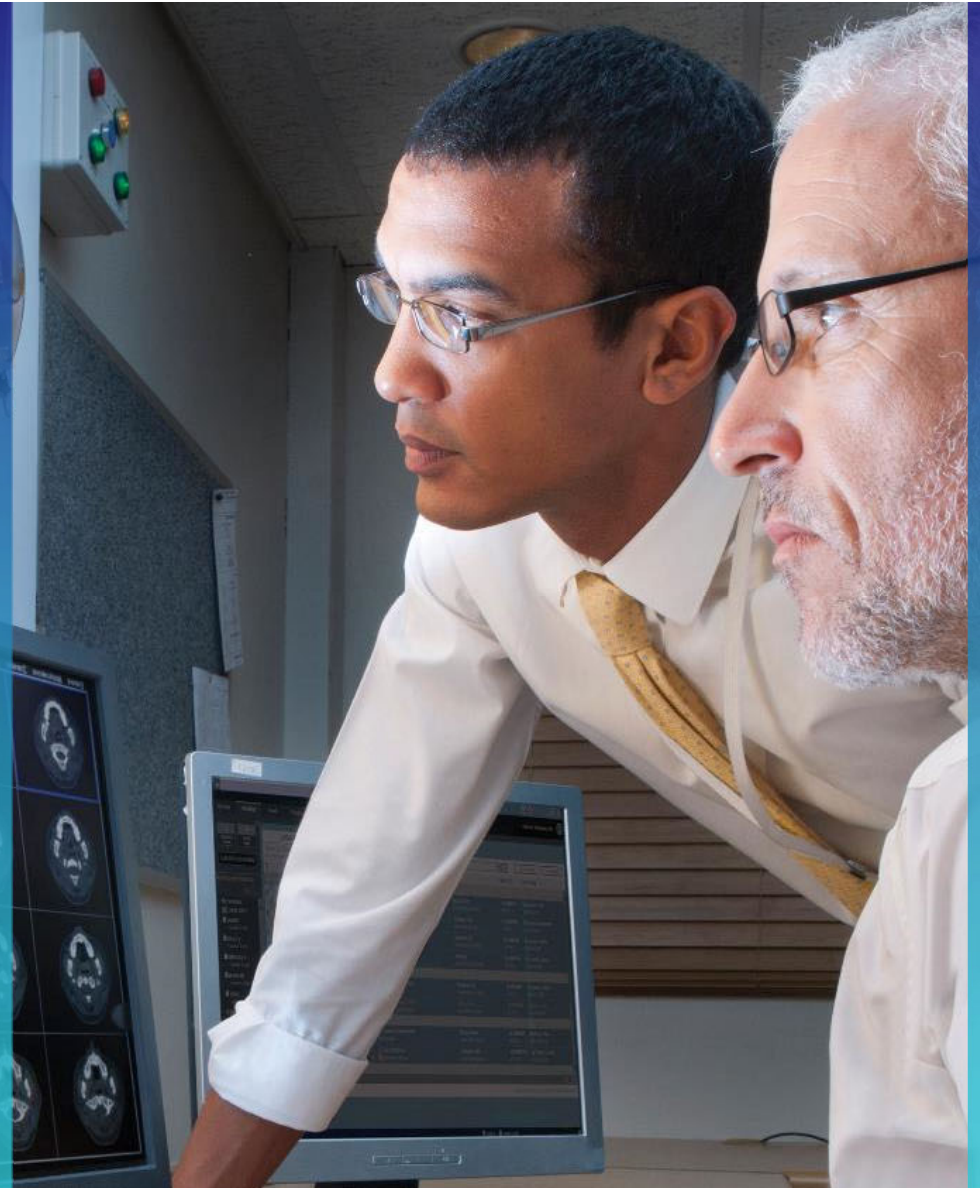
AI MEDICAL DEVICE TRANSPARENCY

KEITH J. DREYER, DO, PHD, FACR, FSIIM
Chief Science Officer, ACR Data Science Institute
Chief Data Science Officer, Mass General Brigham
Associate Professor, Harvard Medical School

FDA Patient Advisory Committee Open Public Hearing

**Advancing Health Equity In Medical Devices:
Artificial Intelligence Applications In Healthcare**

September 6, 2023



DISCLOSURES

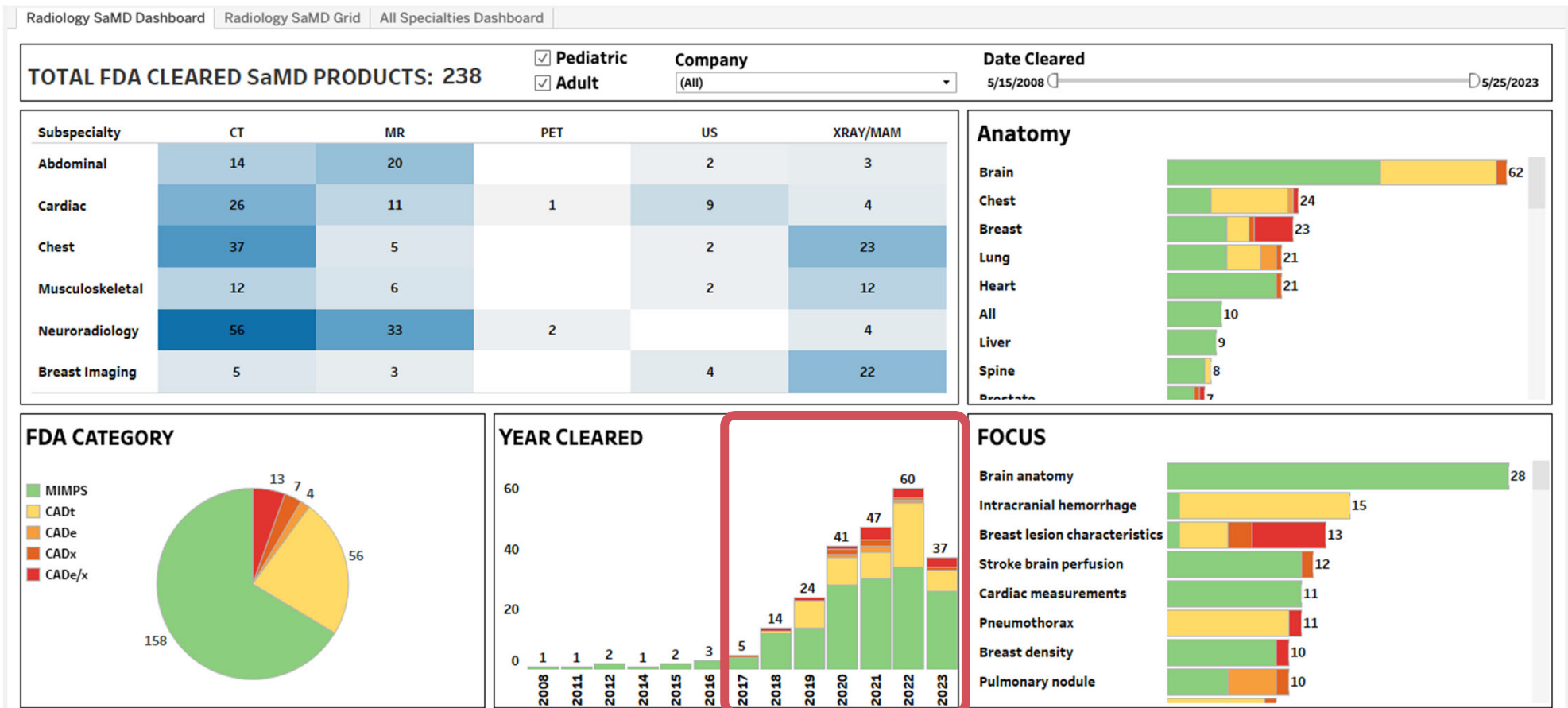
No Commercial Conflicts Of Interest

Neither I nor my immediate family have a financial relationship with a commercial organization that may have a direct or indirect interest in the content of this presentation

Other Disclosures

- Chief Science Officer - ACR Data Science Institute
- Chief Data Science Officer – Mass General Brigham

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ACR DATA SCIENCE INSTITUTE – AICENTRAL.ORG

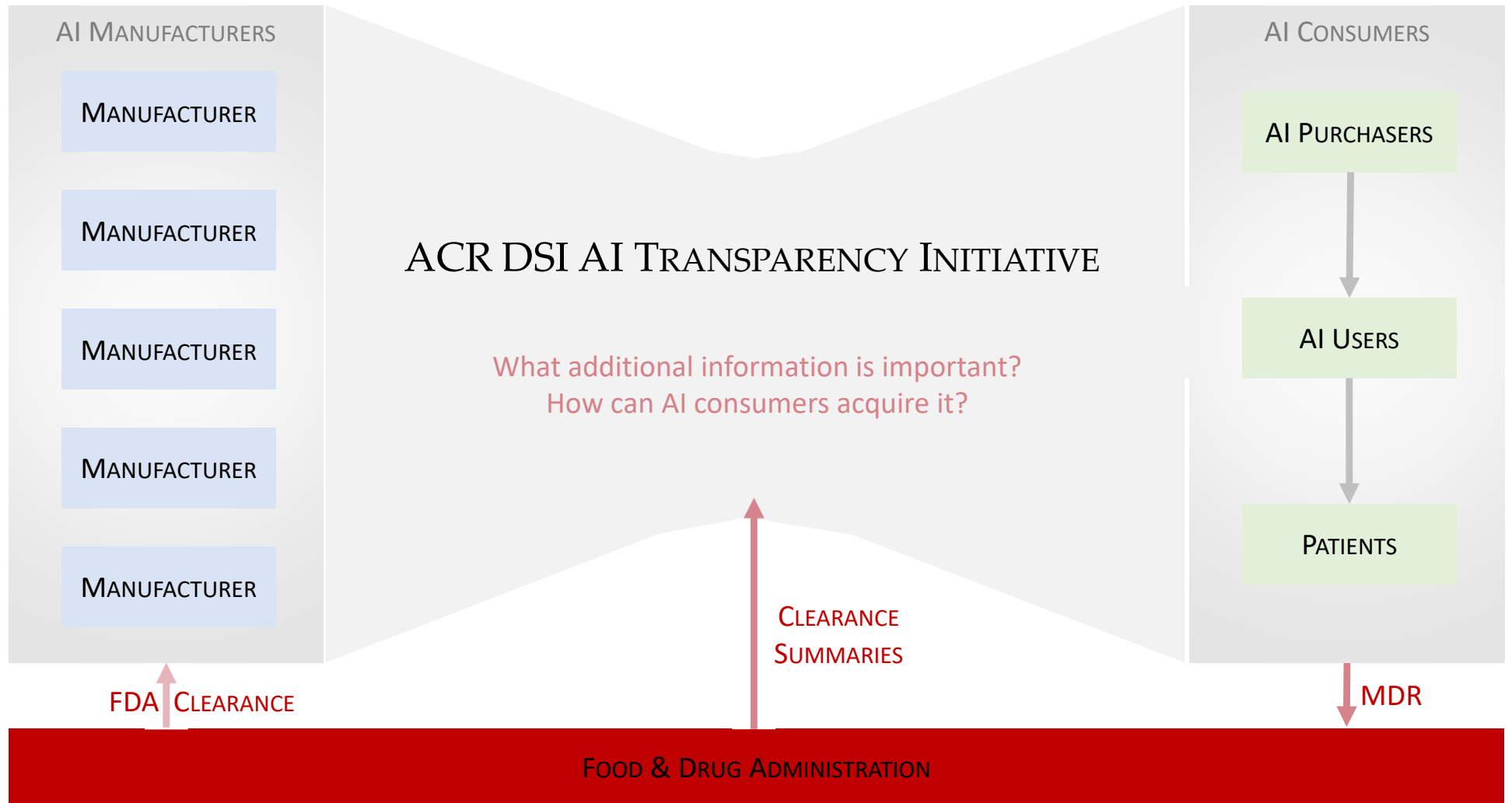
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100's

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ACR DSI AI TRANSPARENCY INITIATIVE

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Imaging Algo

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Imaging Algo 2.3

TRANSPARENT AI

Imaging Algo 2.3 offers radiologists tools designed to help them learn the basics of AI and participate directly in the creation, validation and use of health care AI.

Imaging Algo 2.3 will allow radiologists to:

- Learn the basics of AI and explore the use of AI in their practices
- Collaborate on to the development of AI models for diagnostic imaging
- Create AI models tailored to their local patient population

Product Overview | **Transparent AI**

Manufacturer
Cutting Edge AI

Product Code
POK

FDA Cleared Date
2020-06-26

Predicate Device(s)
???

Previous Version(s)
???

Subspeciality
???

Editions
V2.3

Product Overview

Learn
Learn how AI applies to imaging through a series of detailed videos.

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.

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

Publish
Publish your AI model by sending it to an AI marketplace.

Assess
Track and monitor the performance of your deployed AI model.

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

[Contact Vendor](#)

All Products from Cutting Edge AI

- [Imaging Algo 2.3](#)
- [Modern Algo 2.0](#)
- [Visual AI 3.0](#)
- [Image Data 4.0](#)
- [Scan Model 2.0](#)

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Model Identifier

- Company, Product, Version, Clearance Date, FDA Submission Number

Model Type

- Product Category, Additional Information

Model Characteristics

- Inclusion Criteria, Exclusion Criteria, Instructions for Use, Additional Information

Indications for Use

- Clinical Output, Intended User, Patient Age, Body Area, Modality, Additional Information

Model Performance

- Study Type, Reference Standard, # of Readers, # of Cases (# +/-), Age Range, Gender Ratio
- Race/ethnicity Ratio, Geographic breakdown, Manufacturer list, Scanner list
- Number of sites, % +/- findings, Accuracy, Specificity, Additional Information

Training Data Set

- # of Cases, Age range and distribution, Gender ratio, Race/ethnicity ratio
- Geographic breakdown, Manufacturers, Scanners, Additional Information

Model Limitations

- Supported scanners/manufacturers, Slice thickness, Supported hardware
- Contrast agent, MRI field strength, Reconstruction kernel, Additional Information

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Transparent-AI Data Elements

Appendix				
Type	Element Name	ID	Description	Required
Model Identifier	Company name	MI.1	Name of company.	Yes
	Product name	MI.2	Name of FDA cleared product.	Yes
	Product version	MI.3	Version of the Algorithm used for inference.	Yes
	Product clearance date	MI.5	Date the product was cleared by FDA.	Yes
	Product FDA submission number	MI.6	Unique FDA ID that is referred as submission number.	Yes
	Additional information	MI.7	Free text field.	No
	Model Type	Product category	MT.1	Indicate CAD type the product is cleared for.
Additional information		MT.2	Free text field.	No
Model Characteristics	Data inclusion criteria	MC.1	Indicate the inclusion criteria for the product to run and provide output.	Yes
	Data exclusion criteria	MC.2	Indicate the exclusion criteria where the product will not run.	Yes
	Instructions for use	MC.3	Indicate if your company will be able to provide instructions for use document.	Yes
	Additional information	MC.4	Free text field.	No
Indications for Use	Clinical output	IU.1	What is the finding(s) that the product is intended to output	Yes
	Intended user	IU.2	Indicate the intended user of the product.	Yes
	Patient age	IU.3	Age group the product cleared is cleared for.	Yes
	Body area	IU.4	What target body part is the product intended for use.	Yes
	Modality	IU.5	Target modality for the product.	Yes
	Additional information	IU.6	Free text field.	No
Model Performance (performance testing and/or reader study)	Study type	MP.1	Indicate Reader Study or Stand-Alone Performance.	Yes
	Reference standard (ground truth)	MP.2	What was the reference standard (ground truth) based on?	Yes

Number of readers	MP.3	If reader study was conducted, how many readers read each case?	No
Number of cases	MP.4	How many image studies were used to evaluate model performance?	No
Number of positive and negative cases	MP.5	Indicate number of positive and negative cases.	No
Age range	MP.6	Indicate age range for data set.	No
Sex ratio	MP.7	Indicate sex ratio of data set.	No
Race/ethnicity ratio	MP.8	Indicate the race/ethnicity breakdown of data set.	No
Geographic breakdown	MP.9	Indicate the geographic breakdown of data set.	No
Manufacturer list	MP.10	Indicate the manufacturers in data set.	Yes
Scanner list	MP.11	Indicate the scanners in data set.	Yes
Number of sites	MP.12	How many sites were used.	No
Percent of cases with and without finding	MP.13	Indicate the percent of positive and negative cases.	No
Model accuracy	MP.14	Indicate the model accuracy.	No
Model sensitivity	MP.15	Indicate the model sensitivity.	Yes
Model specificity	MP.16	Indicate the model specificity.	Yes
Additional information	MP.17	Free text field.	No
Model dataset -- Number of cases	TD.1	Indicate number of cases the model was trained on.	No
Age range the model was trained on as well as age distribution	TD.2	Indicate age range the model was trained on as well as the age distribution.	No
Sex ratio model was trained on	TD.3	Indicate sex ratio the model was trained on.	No
Positive and negative cases	TD.4	Indicate number of positive and negative cases the model was trained on.	No
Race/ethnicity ratio	TD.5	Indicate the race/ethnicity breakdown the model was trained on.	No
Geographic breakdown	TD.6	Indicate the geographic breakdown the model was trained on.	No
Manufacturers	TD.7	Indicate the manufacturers the model was trained on.	No
Scanners	TD.8	Indicate the scanners that the model was trained on.	No
Additional information	TD.9	Free text field.	No
Supported scanners/ manufacturer	ML.1	Indicate if algorithm will only work on specific scanner or manufacturer.	No

ML.2	Indicate if there is a limit on slice thickness for product to perform.	No
ML.3	Indicate if product works only with specific hardware.	No
ML.3	Indicate if the product was cleared for contrast use.	No
ML.4	Indicate if the product was cleared for a specific magnetic field strength.	No
ML.5	Describe the convolution kernel or algorithm used to reconstruct the data.	No
ML.6	Free text field.	No
	List out similar FDA-cleared products to your current product. This may include current predicate and reference devices listed in FDA summary.	No
	Describe how customers can reach out to company when needed	No

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<p>CADI</p> <h3>Imaging Algo 2.3</h3> <p>Imaging Algo offers radiologists tools designed to help them learn the basics of AI and participate directly in the creation, validation and use of health care AI.</p> <p>Cutting Edge AI</p>	<p>MMPs</p> <h3>Modern Algo 2.0</h3> <p>Independently test algorithm performance ahead of any regulatory review by the FDA or other governmental agencies to determine if an algorithm can perform well across device, facilities, and demographics.</p> <p>Cutting Edge AI</p>	<p>CADe</p> <h3>Visual AI 3.0</h3> <p>Discover accessible and meaningful datasets for machine learning practitioners to use for their projects.</p> <p>Cutting Edge AI</p>	<p>CADe</p> <h3>Scan Model 2.0</h3> <p>Accelerate the process of vetting commercially available AI models by exploring the algorithm summaries, FDA product codes, and search by body area, modality, or device.</p> <p>Cutting Edge AI</p>	<p>MMPs</p> <h3>Assist</h3> <p>Harness expert and AI-based clinical guidance to enhance traditional open-ended reporting practices. Benefit from structured, standards-based reports for monitoring and tracking findings and recommendations.</p> <p>R</p>
<p>MMPs</p> <h3>Image Data 4.0</h3> <p>Unleash the power of AI by connecting to a vast array of cutting-edge AI applications tailored to your needs.</p> <p>Cutting Edge AI</p>	<p>CADI</p> <h3>Modern Algorithm V2.3</h3> <p>Experience the next generation of medical diagnostics with our groundbreaking AI algorithm for chest x-ray classification. Achieve unparalleled accuracy and speed in detecting abnormalities.</p> <p>Modern Algorithm, Inc.</p>	<p>CADe</p> <h3>CT Head Triage Algorithm</h3> <p>Revolutionize emergency medicine with our state-of-the-art AI algorithm for CT head triage. Streamline the assessment process, prioritize critical cases, and expedite patient care.</p> <p>Triage Algorithms, Inc.</p>	<p>CADI</p> <h3>Format AI</h3> <p>AI to analyze anterior and posterior portions with multiple formats, like DICOM, TIFF, Leica, etc.</p> <p>DR DIGITAL RADIOLOGY</p>	<p>Cardiac Imaging</p> <h3>Algo Scan</h3> <p>Deploy accurate FDA-approved AI models. Speed up analyzing medical imaging and establishing diagnoses with DR AI tools.</p> <p>DR DIGITAL RADIOLOGY</p>
<p>CADI</p> <h3>Accurate AI Filters</h3> <p>Algorithm can be filtered based on the density and shape of products and contaminants.</p> <p>Accurate AI</p>	<p>MMPs</p> <h3>Accurate AI Search</h3> <p>Randomized Algorithms Sorting Algorithms Searching Algorithms Hashing Algorithms</p> <p>Accurate AI</p>	<p>CADI</p> <h3>Data Labeling</h3> <p>Protect personal health information and prepare data appropriately for training and testing algorithms. AI Data Labeling has developed significant experience through clinical trials networks.</p> <p>Accurate AI</p>	<p>CADe</p> <h3>MD Analysis</h3> <p>Making one-to-one comparisons with a common language used across our AI products. MD Analysis is beneficial for organizations because it is based on a collection of common radiology terms and semantic structures.</p> <p>MD Algos</p>	<p>MMPs</p> <h3>ClearRead AI</h3> <p>ClearRead AI automatically detects and measures properties of solid, part-solid, and ground-glass nodules, suppressing normal structures in chest CTs</p> <p>RiverRain</p>

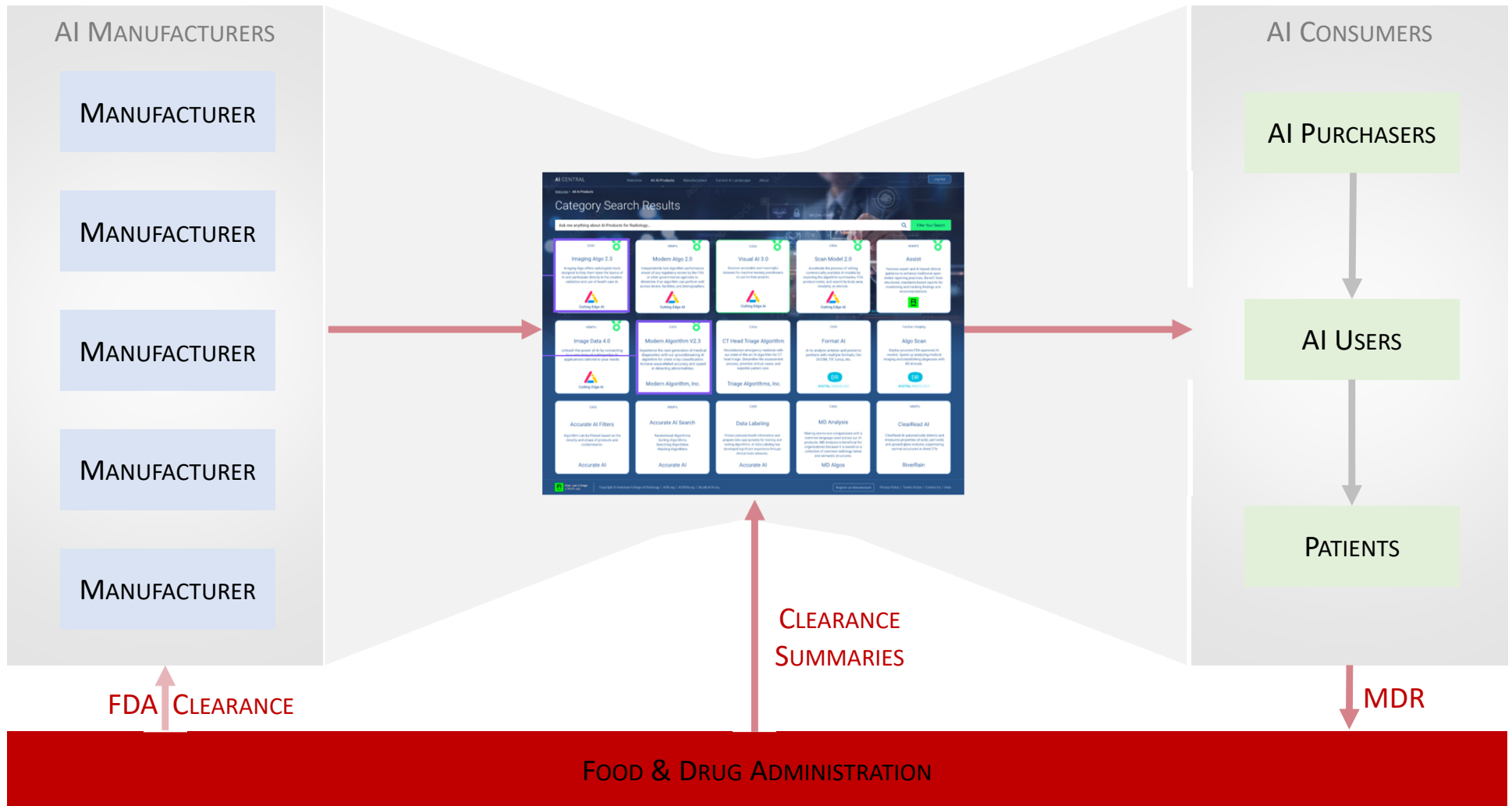
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100's

10,000's



The background image shows two men in a clinical or hospital setting. They are looking at a large monitor displaying medical scans, likely CT or MRI images of a head. The man on the left is younger with glasses, and the man on the right is older with glasses and a beard. The entire image has a blue color overlay.

SUMMARY

For the advancement of health equity in medical devices, it is imperative for manufacturers to disclose information beyond that which is in the public domain, enabling providers to execute informed and judicious decisions on behalf of their patients.

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