AI Medical Device Transparency

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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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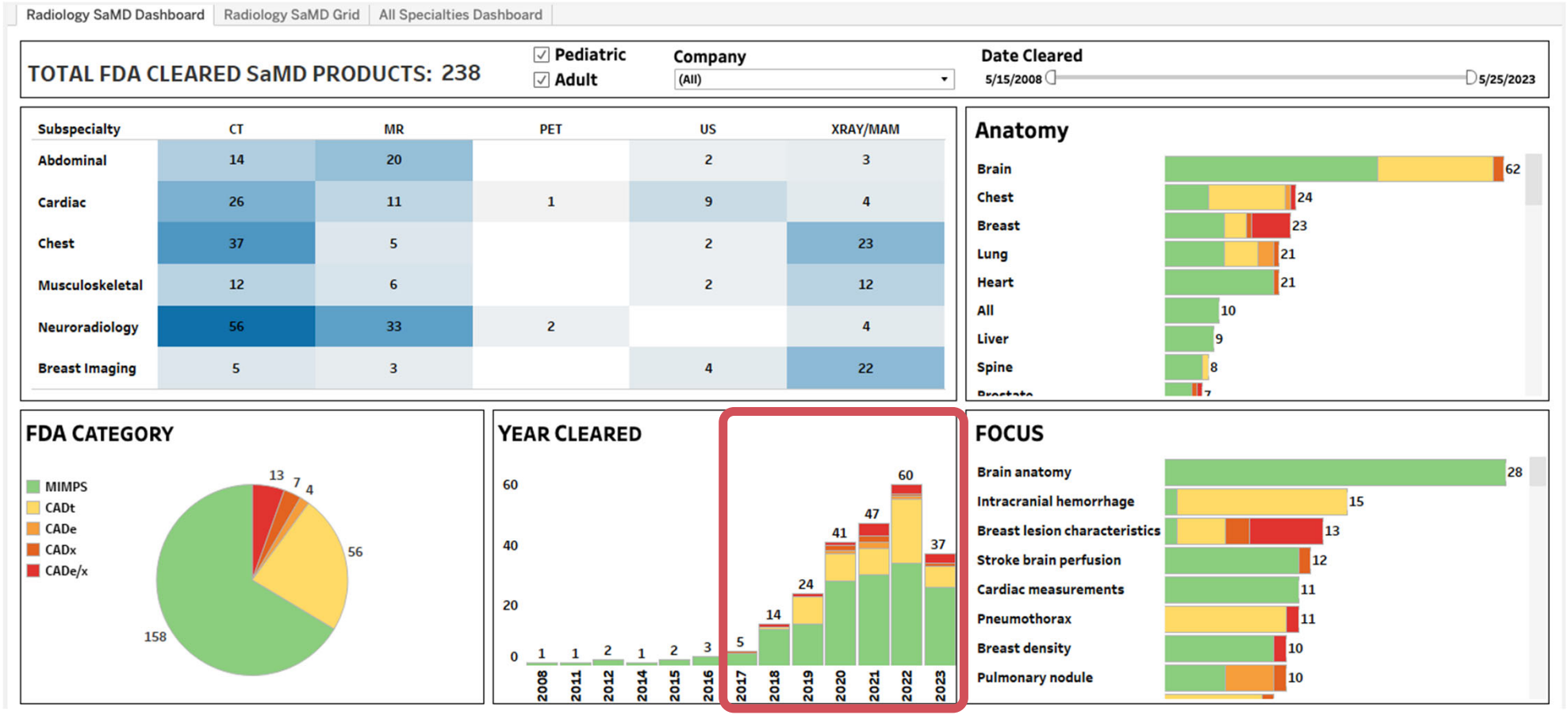

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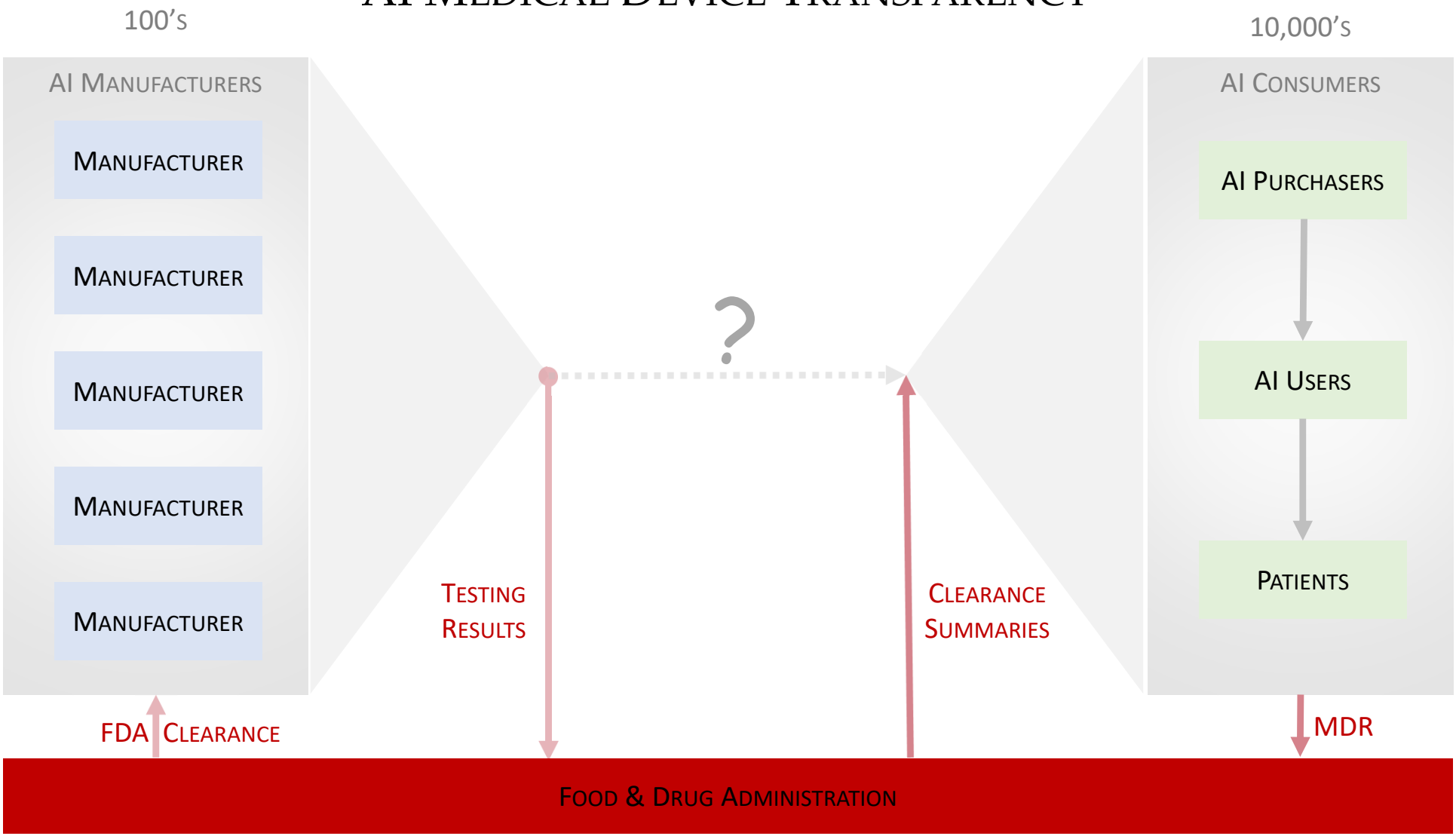

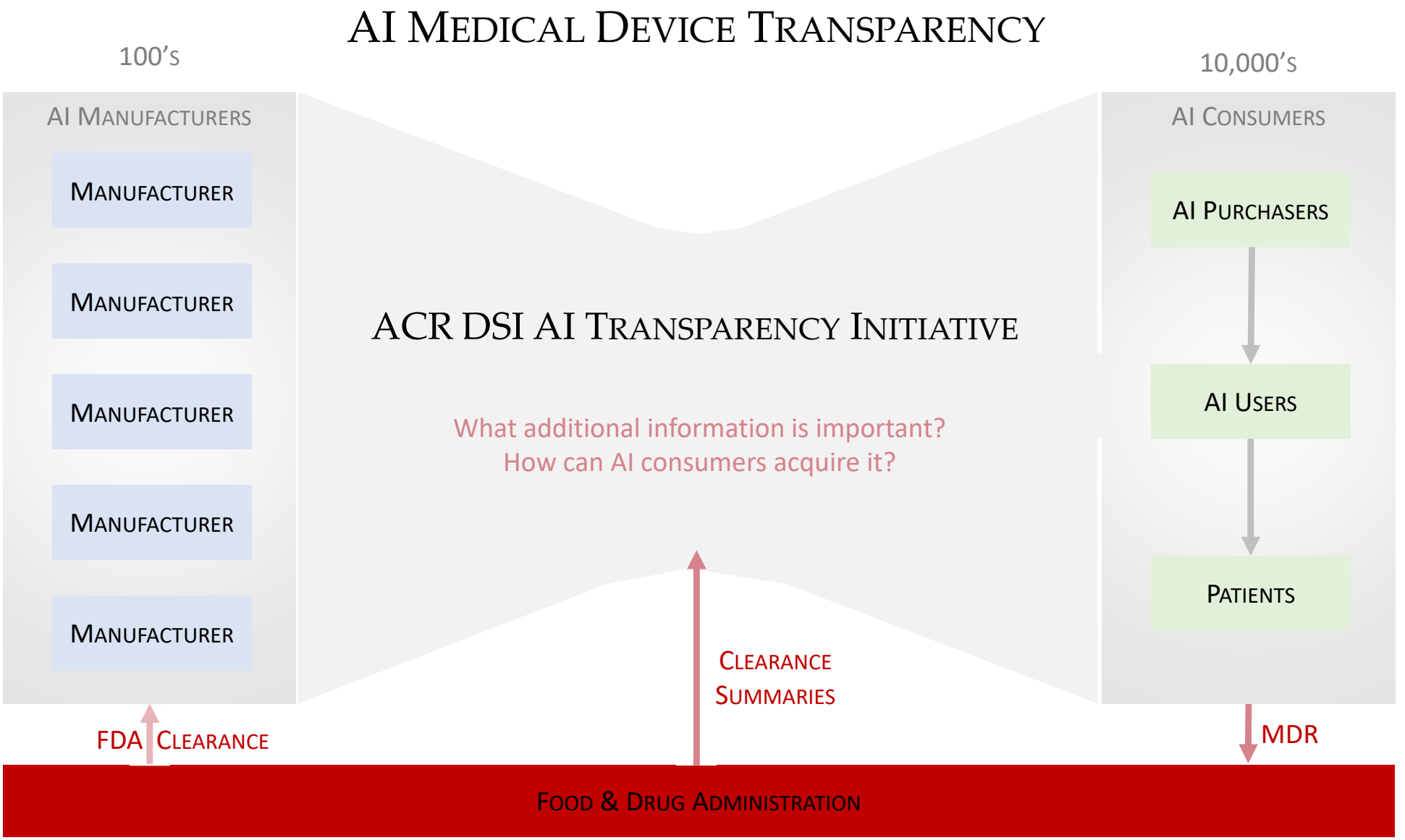
AI Medical Device Transparency
100's
AI Manufacturers
Manufacturer
Manufacturer
Manufacturer
Manufacturer
Manufacturer
10,000's
AI Consumers
AI Purchasers
AI Users
Patients
ACR DSI AI Transparency Initiative
What additional information is important?
How can AI consumers acquire it?
Clearance Summaries
FDA Clearance
MDR
Food & Drug Administration

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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.	Yes
	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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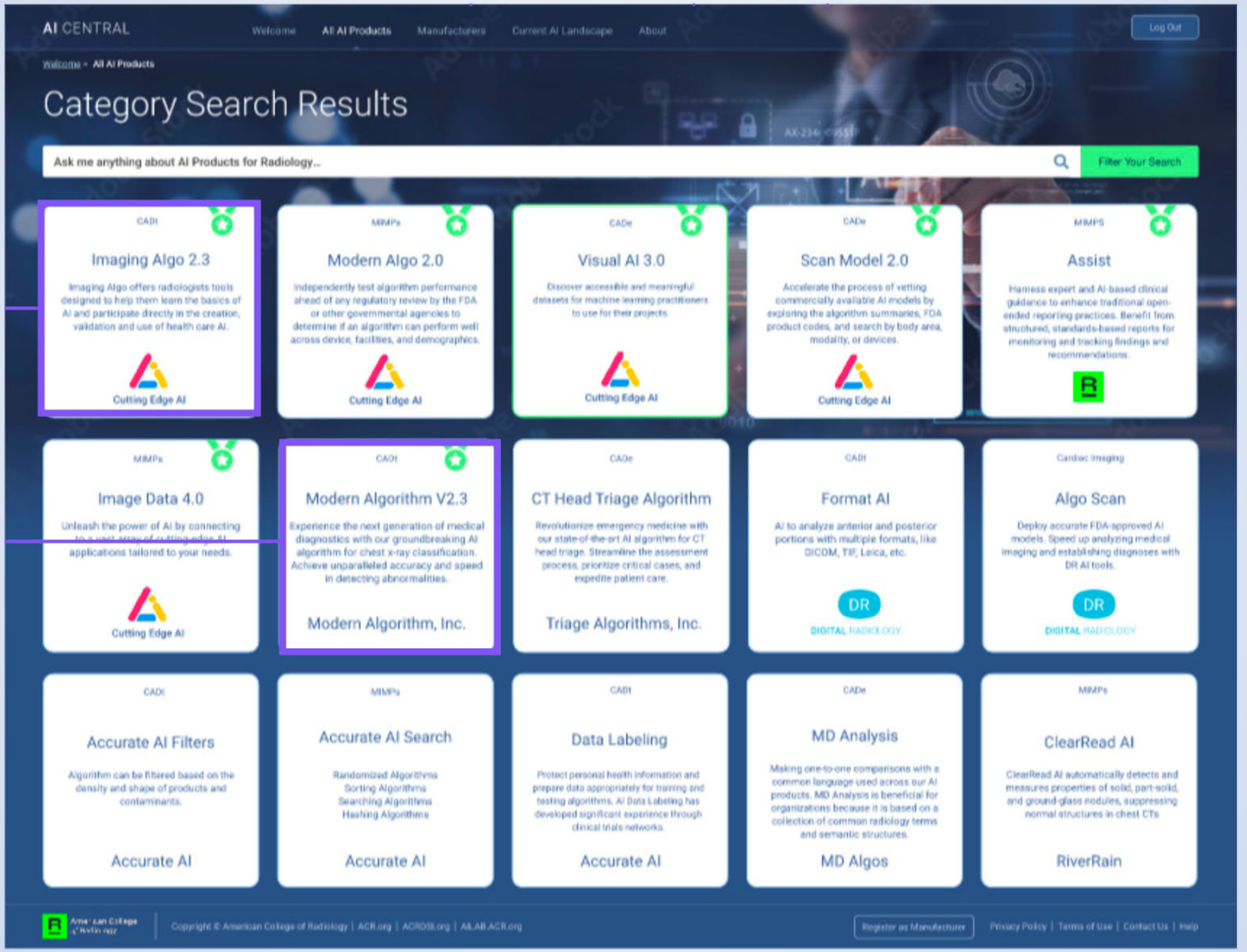

AI Medical Device Transparency

100's

AI Manufacturers

Manufacturer

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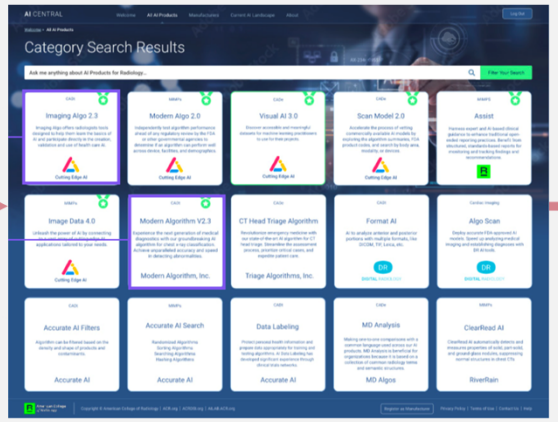

10,000's

AI Consumers

AI Purchasers

AI Users

Patients

FDA Clearance

Clearance Summaries

MDR

Food & Drug Administration

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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