A.I. for Medicare Requires a Change in Medical Device Regulation

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出版情報：pp.1-, 2018-01-10
バージョン：
権利関係：

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January 10, 2018 at Kyushu University

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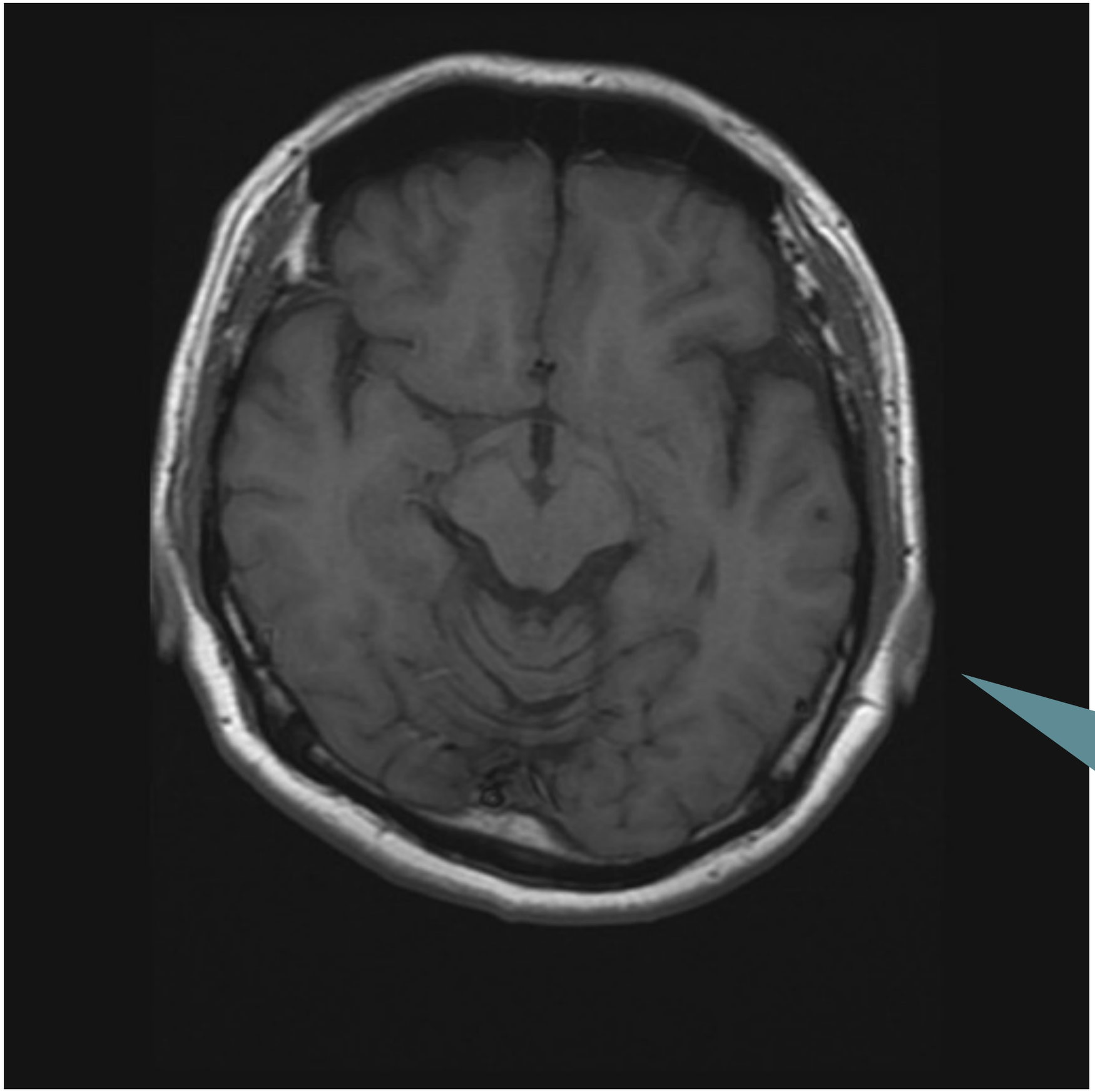
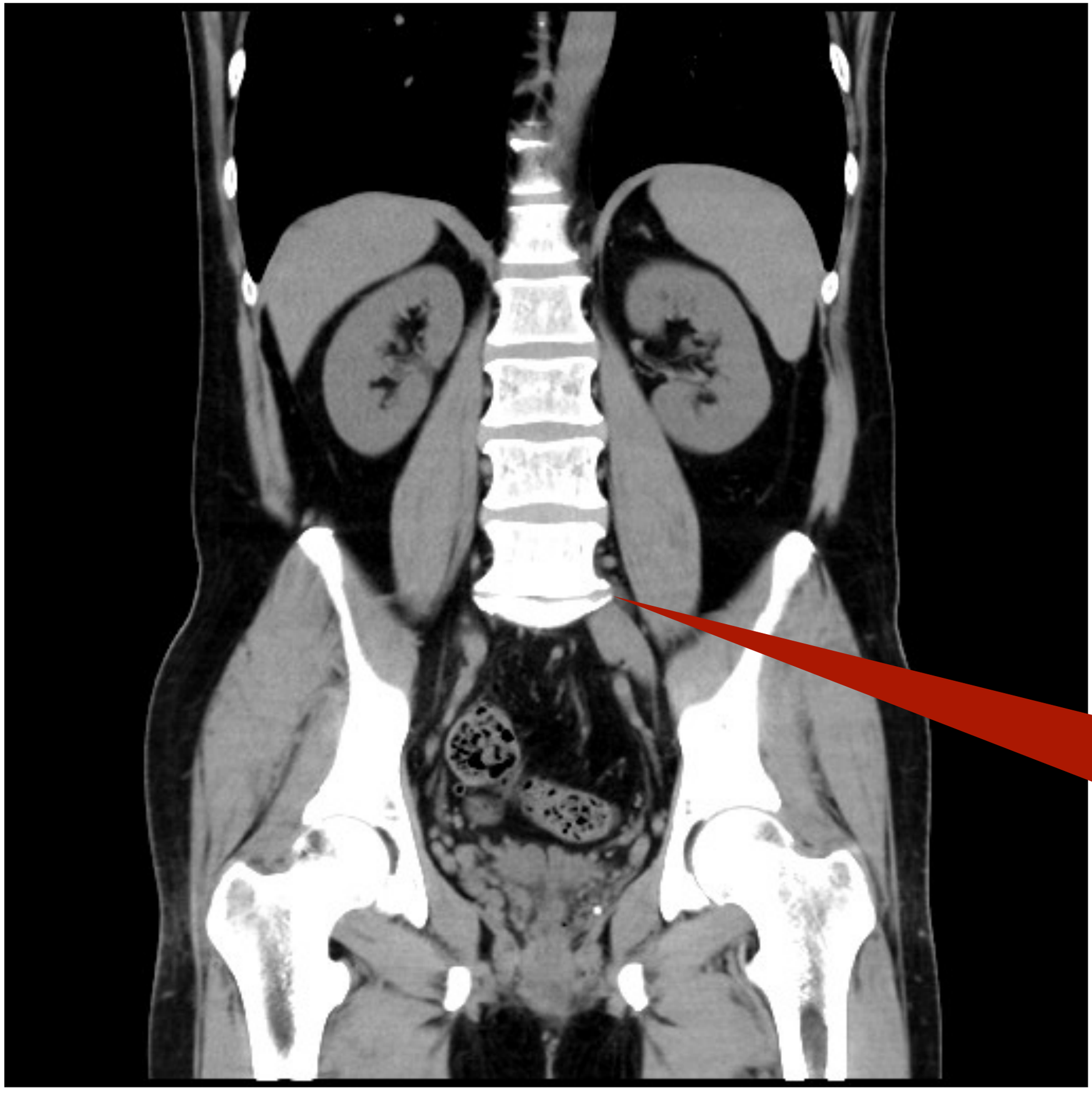


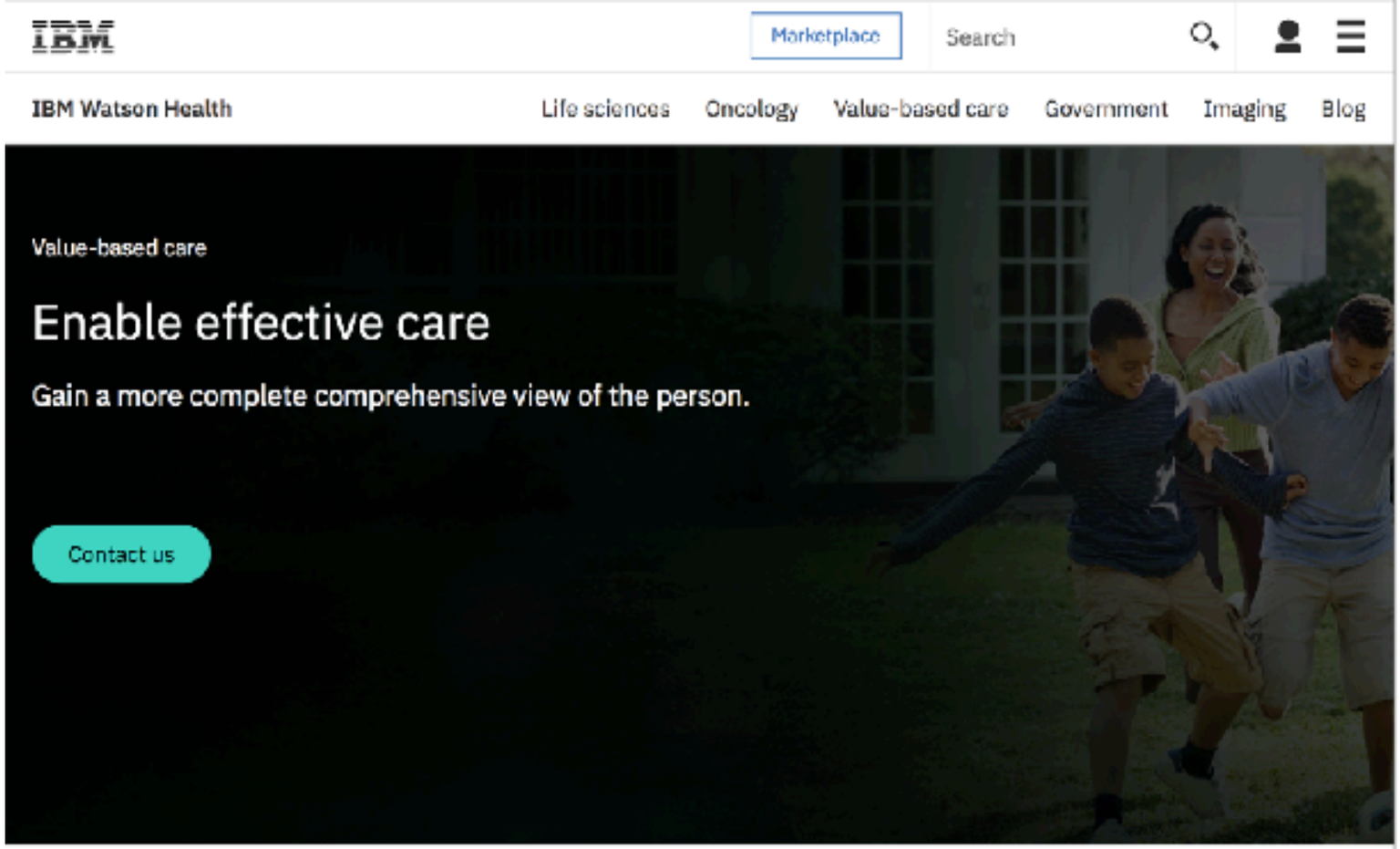
(MR image)
No trace of
brain infarct



(CT image)
Worn cartilage
- a cause of
back pain

The Role of Artificial Intelligence in Medical Care.

- A.I. helps physicians to conduct diagnosis based on …
  - Dialogue with patients
  - Symptoms of patients
  - Vital data of patients
  - Biopsy data of patients
  - Past medical and/or health data of patients
  - Medical image of patients, etc.



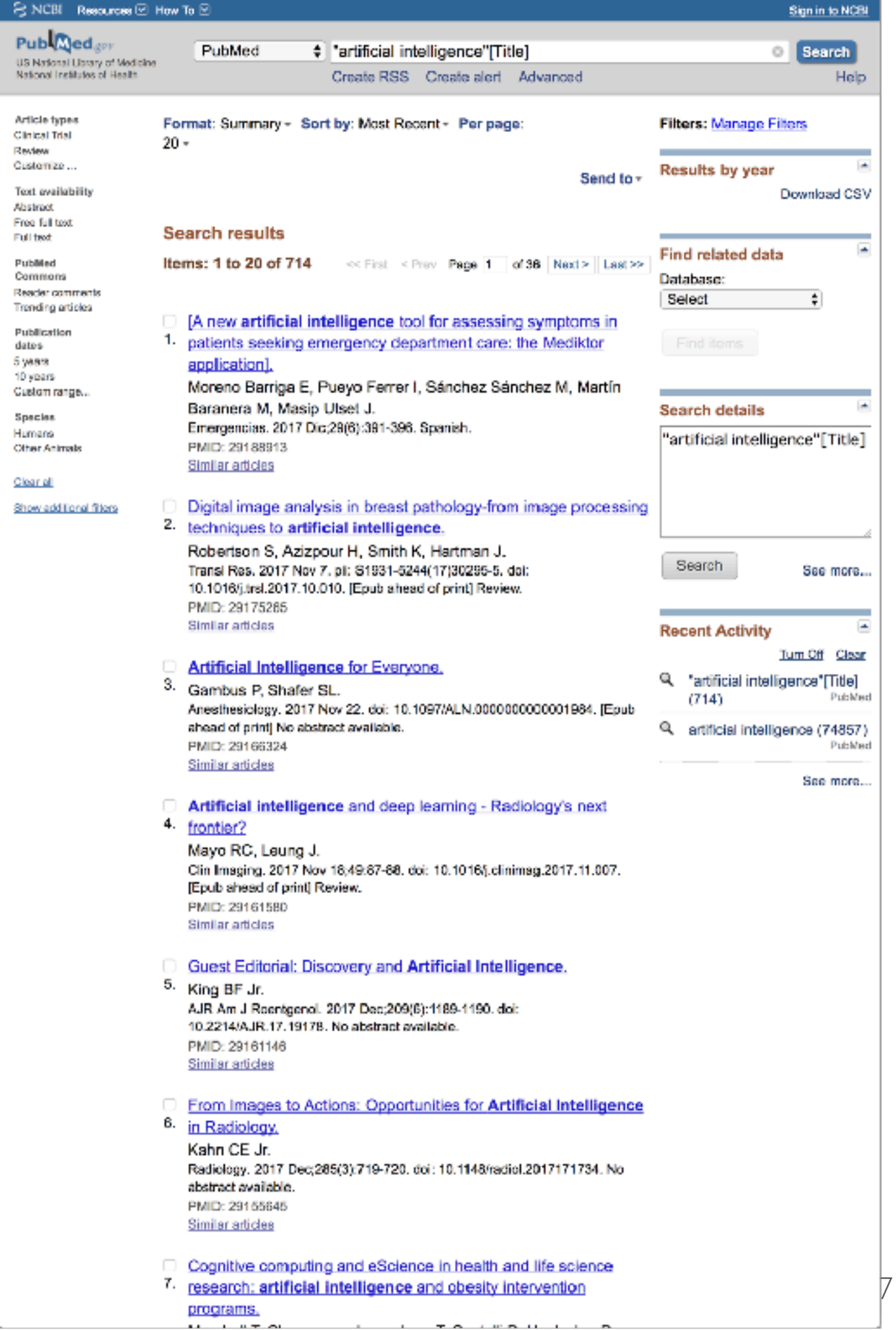
Support better-informed, more effective patient care, health plans, wellness programs, and value dossiers by looking at a comprehensive view of the factors that influence a person's health - including socioeconomic status, environment, social support a access to health care.

Talk to an expert

Benefits

- Point-of-care decision support
- Evidence-based care standards
- Quality Improvement Programs: patient safety
- Care variability reduction program
- Team based care methodology and implementation support

- https://www.ibm.com/watson/health/value-based-care/enable-effective-care/



- https://www.ncbi.nlm.nih.gov/pubmed/?cmd=HistorySearch&querykey=2

The Purpose of Medical Device Regulation.

- Here, I refer to **The Law on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical devices** of Japan (Law No. 145 of 1960, as amended, often abbreviated as “Yakki-ho” in Japanese).

- “Yak” denotes pharmaceuticals.

- “Ki” denotes medical devices.

Article 1 (Purpose of This Law) of "Yakki-ho"

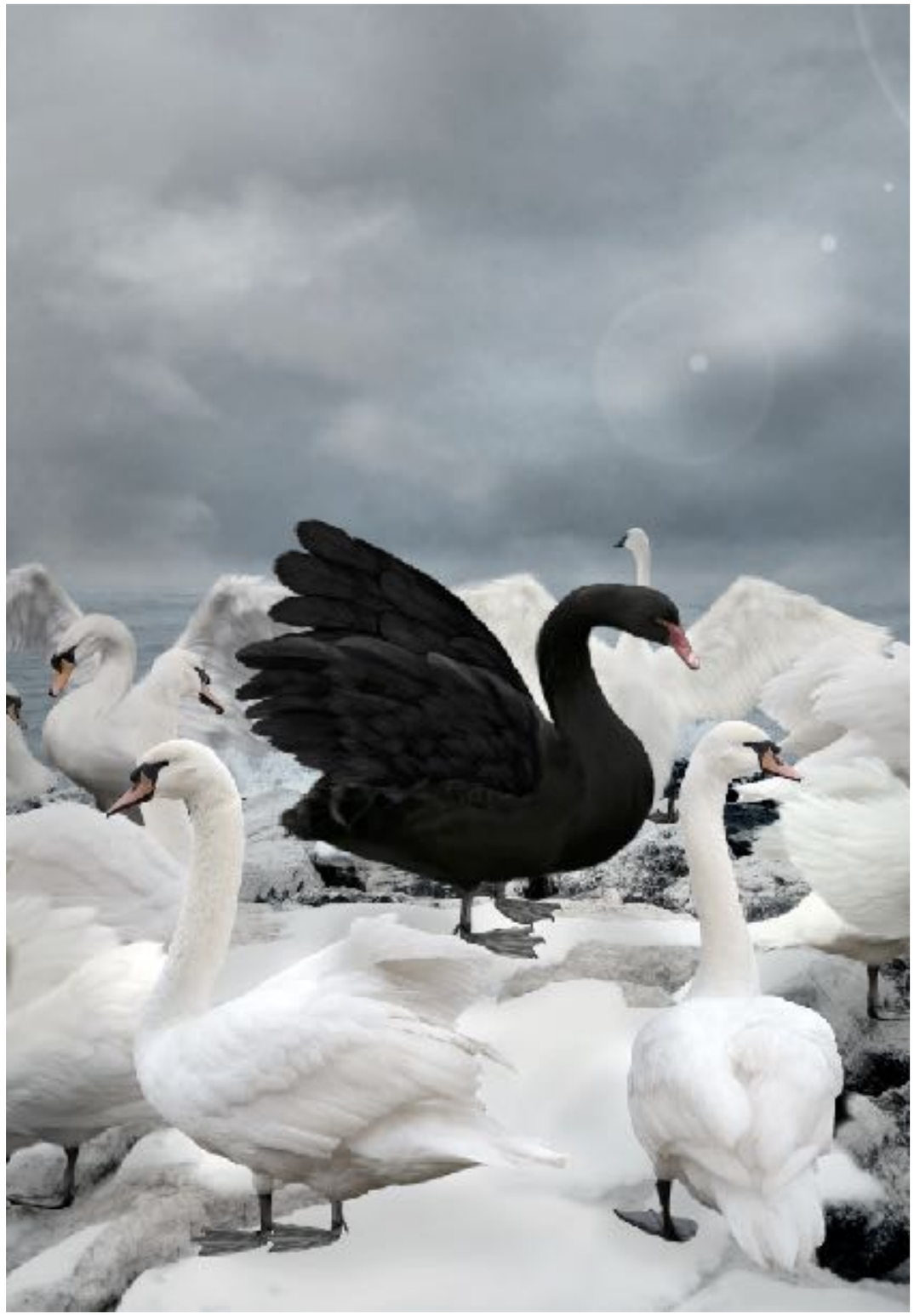
- The purpose of this Law is **to secure** the quality, efficacy and **safety** of pharmaceuticals, quasi-drugs, cosmetics, **medical devices**, regenerative medicine products (hereinafter referred to as "pharmaceuticals"), **to provide the control required for preventing the occurrence or spread of hazards to public health and hygiene caused by the use of such pharmaceuticals**, to take measures against designated substances, and to improve public health and hygiene by taking necessary measures for the promotion of research and development of pharmaceuticals, medical devices and regenerative medicine products which are especially important for medical practice.

- In many jurisdictions, the production and marketing of medical devices is subject to the requirement of giving notice to the government, accreditation by the government or legally certified institution, approval of the government, etc.
    - *See e.g.*, The Global Harmonization Task Force (GHTF) of the International Medical Device Regulation Forum (IMDRF).
        - http://www.imdrf.org/ghtf/ghtf-archives.asp
- These regulations seek to warrant that medical devices are safe and harmless at the time of their delivery to hospitals and clinics.

GHTF Classification	Class I	Class II	Class III	Class IV
Risk	Extremely low risk	Low risk	Medium risk	High risk
Example	X-Ray film	MRI, digestive catheters	Artificial bones, dialyzer	pacemaker, artificial heart values
Regulation under "Yakki-ho"	Self declaration to the Minister	Third party certification		Minister's approval

See e.g., https://www.pmda.go.jp/review-services/drug-reviews/about-reviews/devices/0013.html

An Essential Difference between A.I. for Medical Care and Conventional Medical Device.



	A.I. for Medical Care	Conventional Medical Devices
The conditions upon delivery to hospitals and clinics	The capability of A.I. is limited by the knowledge base that A.I. has already learned.	Perfect conditions are expected.
Change over time	Adequate continuous learning is likely to make A.I. increasingly useful.	Simply deteriorating.
	Inadequate or lack of learning is likely to make the capability of A.I. deteriorate.	
Warranties and maintenance	Continuous learning using a national knowledge base can be provided by the vendor.	The vendors provides limited-time warranty and, if appropriate, continuous maintenance.
	Hospitals and clinics themselves are responsible for the learning based on inhouse or local EHRs.	

Diagnostic Process is
Often Highly Dependent on
Patient's Social Context.

Hospitals and clinics themselves are responsible for the learning based on inhouse or local EHRs.

PATIENT 1

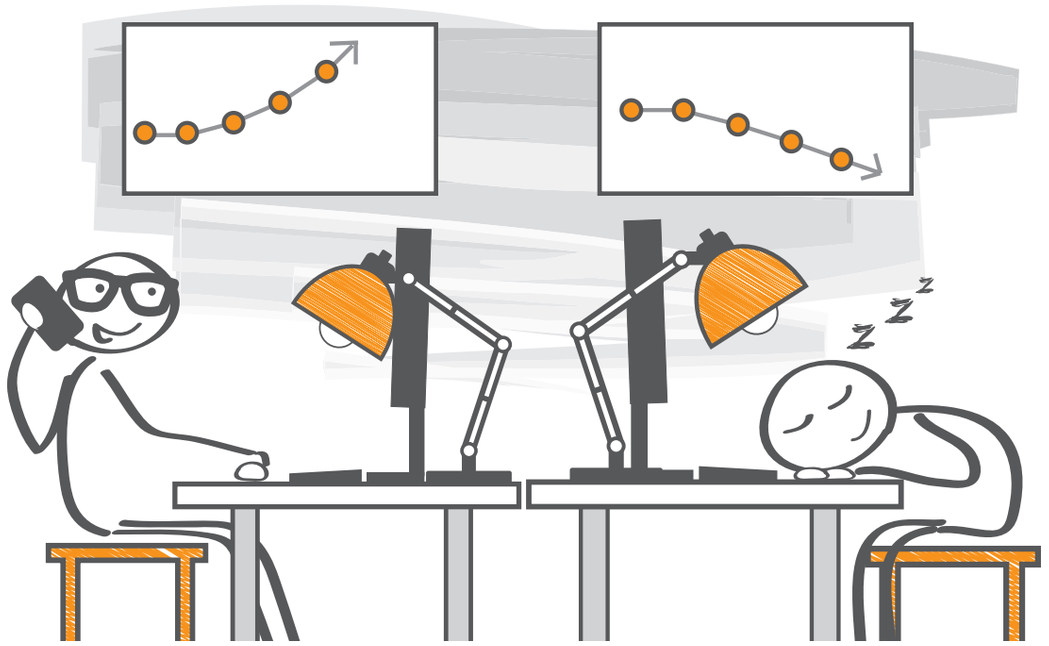
Mr. B is a previously healthy 70-year-old man who underwent right upper lobectomy for localized squamous cell lung cancer 5 days ago. On morning rounds, he comments that he is in a military barracks and that he is ready to go home.

- An example of delirium or dementia shown in a book edited and published **in the U.S.**
  - Scott D.C. Stern, et.al. "Symptom to Diagnosis - An Evidence Based Guide" 3rd ed., Lange Medical Books, Kindle, 9896/30871.

The patient, who was a public prosecutor in Japan, insisted that he had been arrested and was in a police car, although he was actually being raced to hospital in an ambulance.

- My personal experience of delirium or dementia of **an ex-public prosecutor in Japan.**

Some Hospitals Ensure that A.I. Keeps Learning Adequately, while Others Not.



How Can We Redesign Medical Device Regulation?

Who Should be Responsible for Ensuring that A.I. Keeps Learning?

- Social monitoring of A.I. for medical care?
- Mutual monitoring between A.I.s?
- Or, otherwise?

Thank you.

Acknowledgements

This work constitutes a part of the joint research project "Actualize Energetic Life by Creating Brain Information Industries," which is funded by the ImPACT Program of the Council for Science, Technology and Innovation (Cabinet Office, Government of Japan) (http://www.jst.go.jp/impact/en/program/11.html), and seeks to derive knowledge about human brain, for application in industry, by analyzing big data on the human brain, including brain images collected from a considerable number of examinees.