



CDRH Center for Devices and Radiological Health



AdvaMed

Advanced Medical Technology Association

US-JAPAN HBD EAST Think Tank Meeting 2023

～日米産官学による医療機器規制調和会議～



Pharmaceuticals and Medical Devices Agency

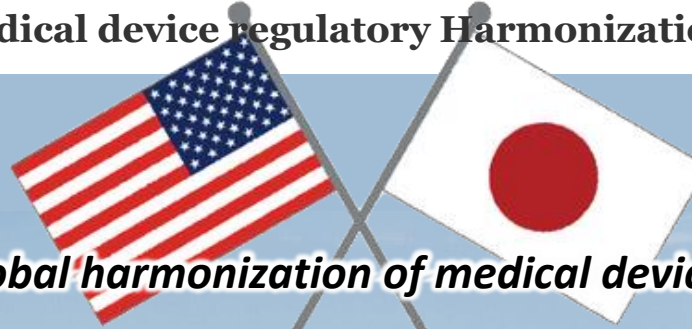


厚生労働省



一般社団法人 日本医療機器産業連合会
JFMDA
The Japan Federation of
Medical Devices Associations

U.S. and Japan medical device regulatory Harmonization by Doing (HBD) initiative



What should be considered for global harmonization of medical device development through HBD activity ?

An overview of the global situation surrounding medical devices

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Chief Medical Officer, MedVenture Partners, Inc

COI

MedVenture Partners, Inc (I serve as a board member)
invests to Sono Motion

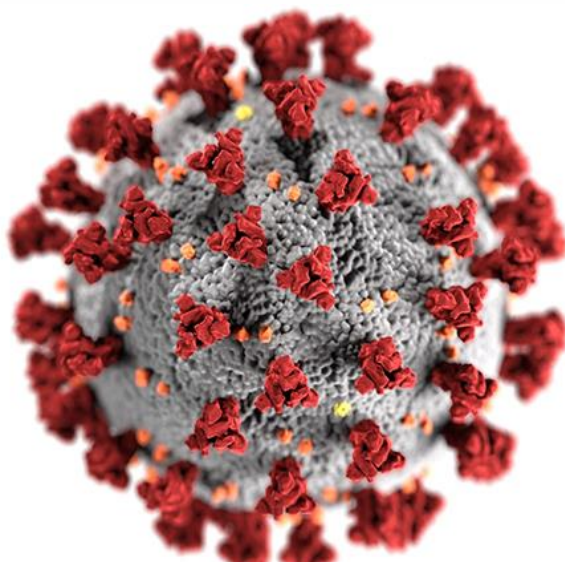


Godzilla



MecaGodzilla

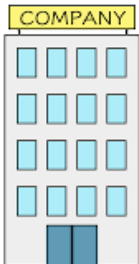
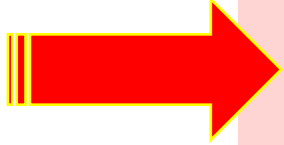
2020



2023



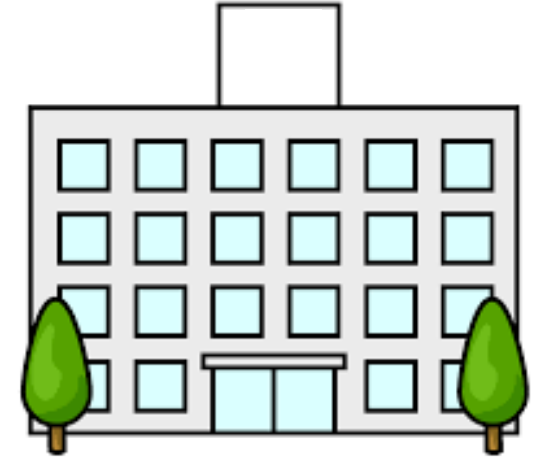
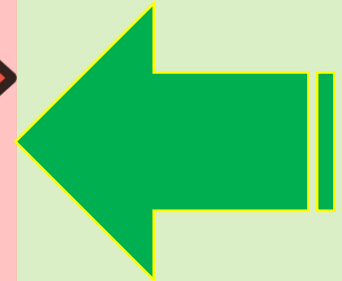
Pandemic



Home



Virtual Hospital Medically Home Remote Care



*Is paradigm shift of healthcare happening
in the USA?*

BEFORE

Most healthcare consultations took place in physical healthcare facilities, such as hospitals, clinics, and doctor's offices.



Telemedicine was often used for minor consultations or in rural areas with limited access to healthcare services.



AFTER

Telehealth and Telemedicine

The pandemic accelerated the adoption of telehealth and telemedicine services. Virtual consultations became more common for routine healthcare needs, allowing patients to access care remotely.



BEFORE



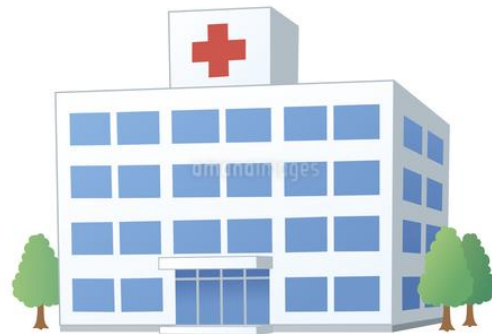
AFTER

Digital Health Tools

The use of digital health tools, including mobile health apps and wearable devices, surged. These tools help individuals monitor their health and communicate with healthcare providers.



BEFORE



AFTER

Remote Monitoring

Remote patient monitoring devices, such as wearable sensors and remote diagnostic tools, gained popularity for managing chronic conditions and tracking vital signs.



BEFORE

精神科



AFTER

Mental Health Awareness

The pandemic has raised awareness about the importance of mental health, both for patients and healthcare providers. Mental health services and resources have become more readily available and destigmatized.



BEFORE



AFTER

Cyber and Data Securities

Cyber and data security are of utmost importance in the medical and healthcare industry, given the sensitive and confidential nature of patient information and the critical role technology plays in healthcare delivery.



BEFORE



AFTER

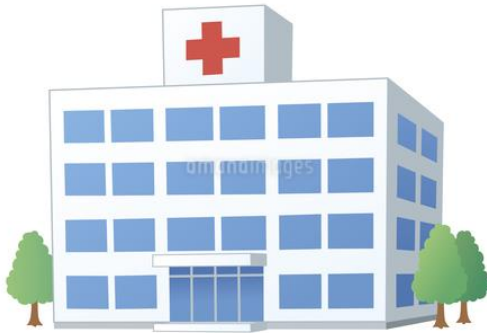
Healthcare Policy Changes

Governments and healthcare organizations have implemented new policies and regulations to address the challenges posed by the pandemic, such as remote work for healthcare professionals, changes in **reimbursement models for telehealth, and pandemic preparedness planning.**



BEFORE

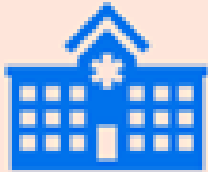
Centralized Clinical Trial



AFTER

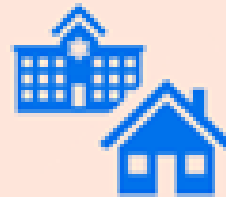
Dx of Clinical Trial





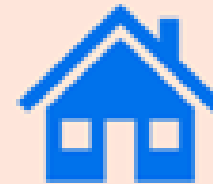
Centralized Clinical Trial

All trial activity
conducted at the clinical
research site



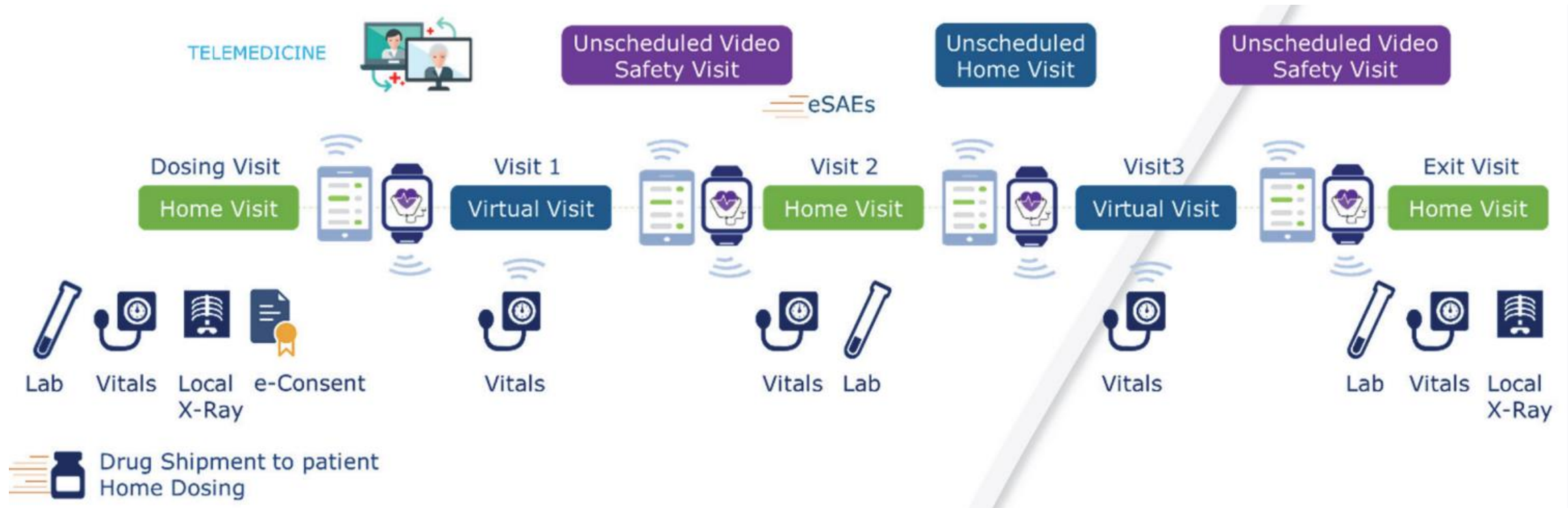
Hybrid Clinical Trial

A combination of trial
activity conducted at the
clinical research site &
participant's home



Decentralized Clinical Trial

All trial activity
conducted at
home/virtually. Medicine
& supplies delivered
directly to participants

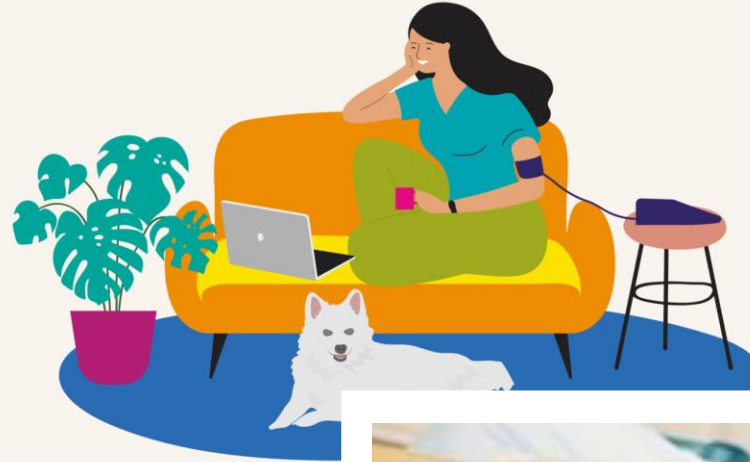




The care of hospital, the comfort of home

NHS

Greater Manchester
Integrated Care



Find out more: gmhospitalathome.co.uk

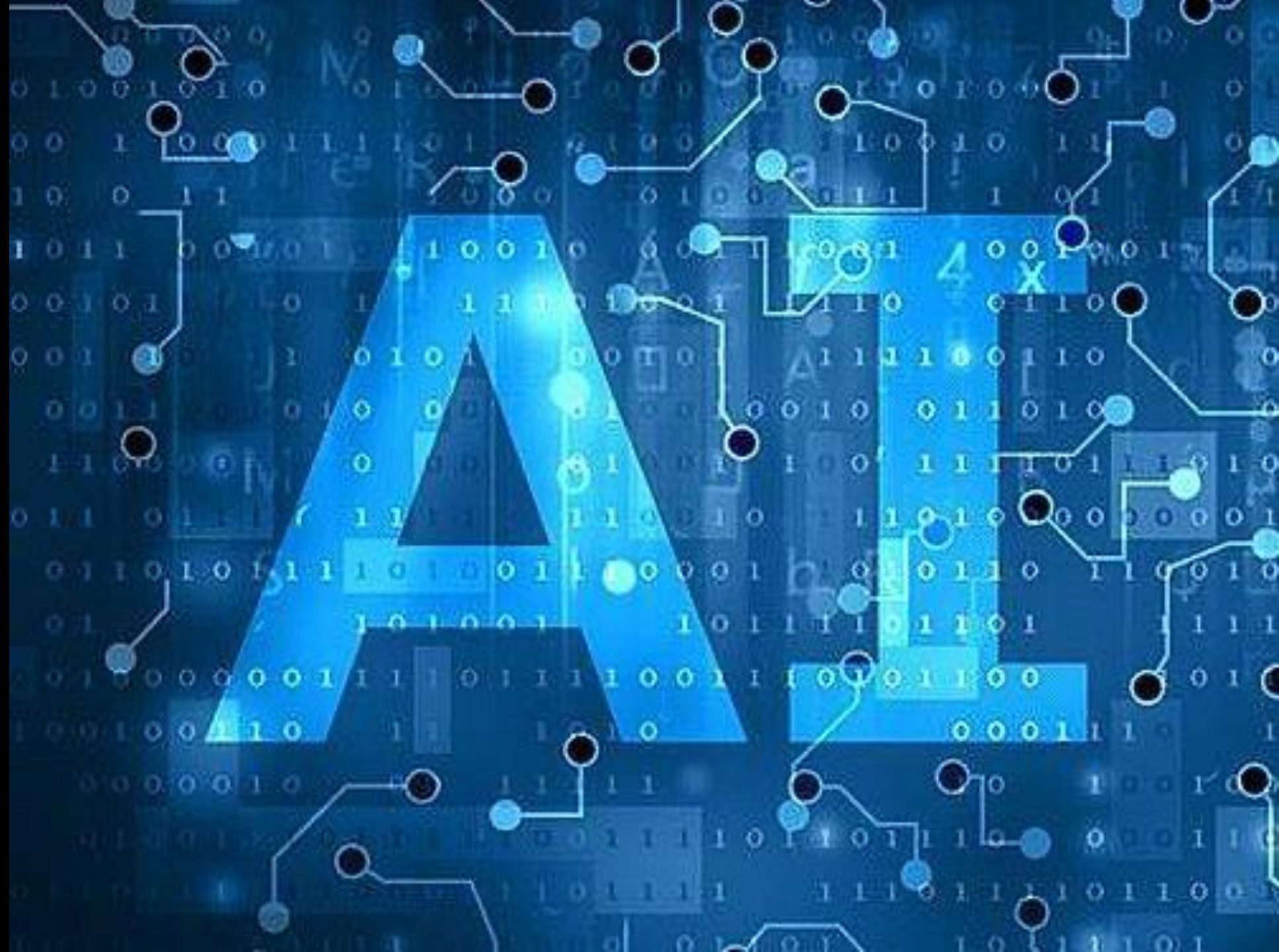


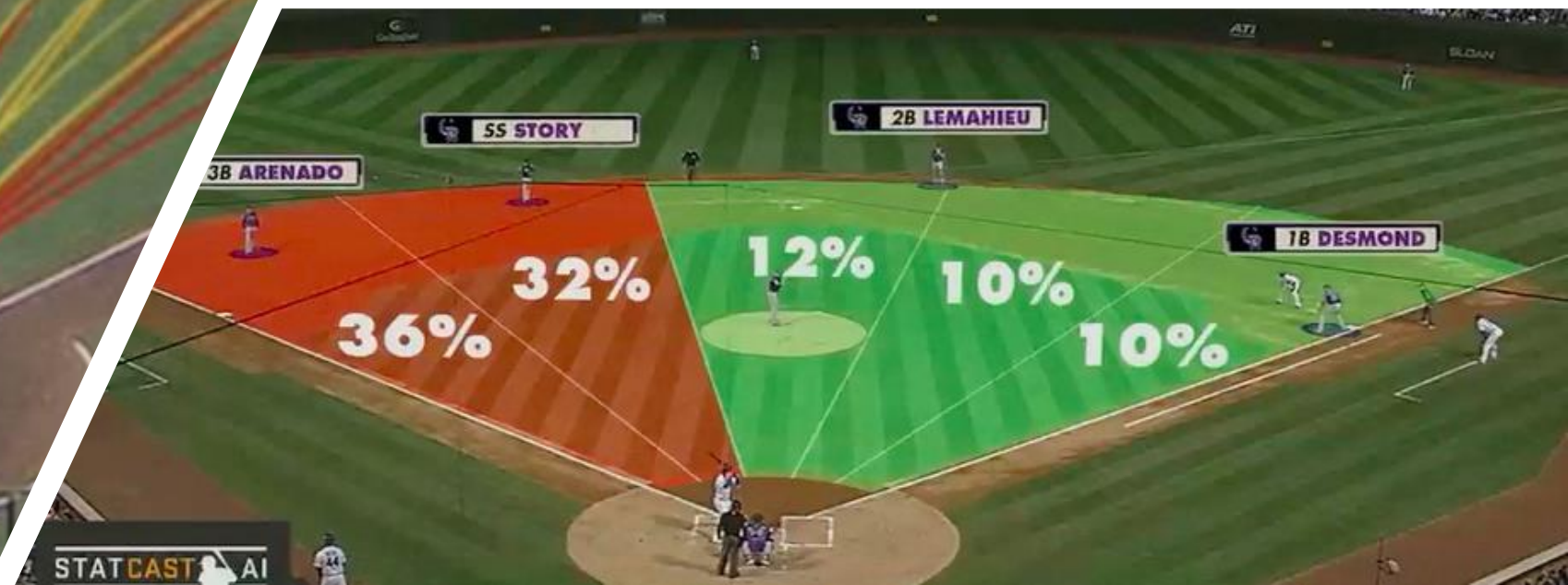
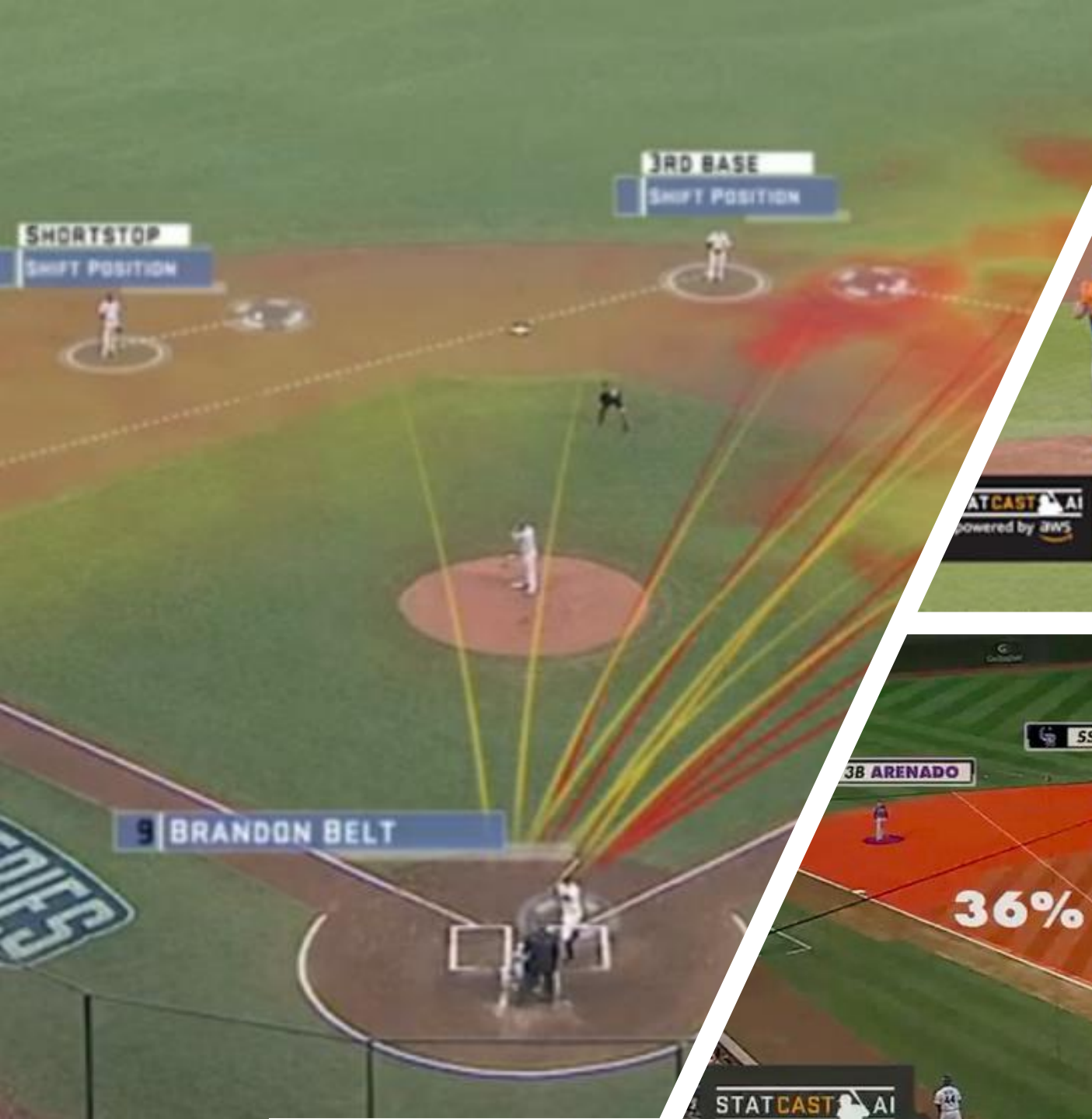
CMS Expanding to
Cover At-Home
Acute Care to Patients

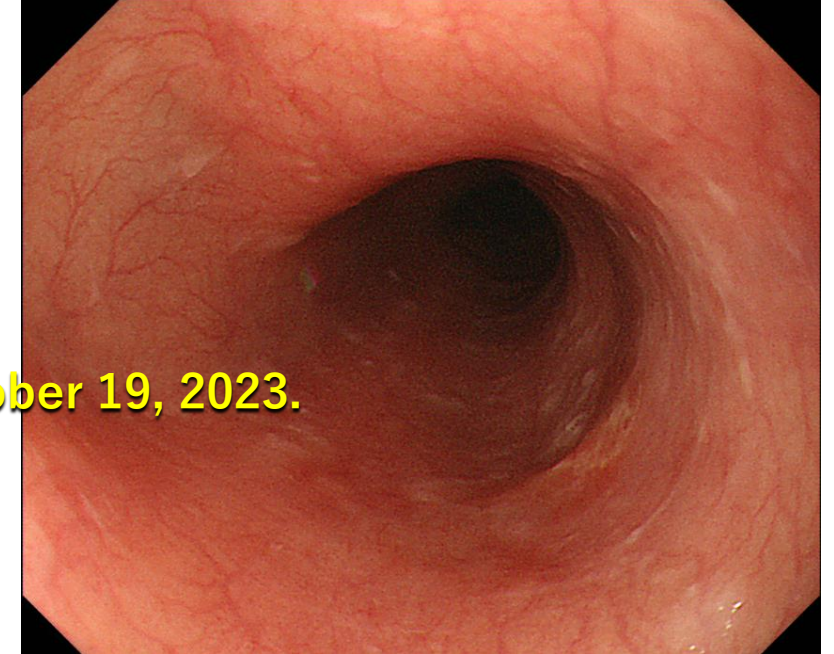
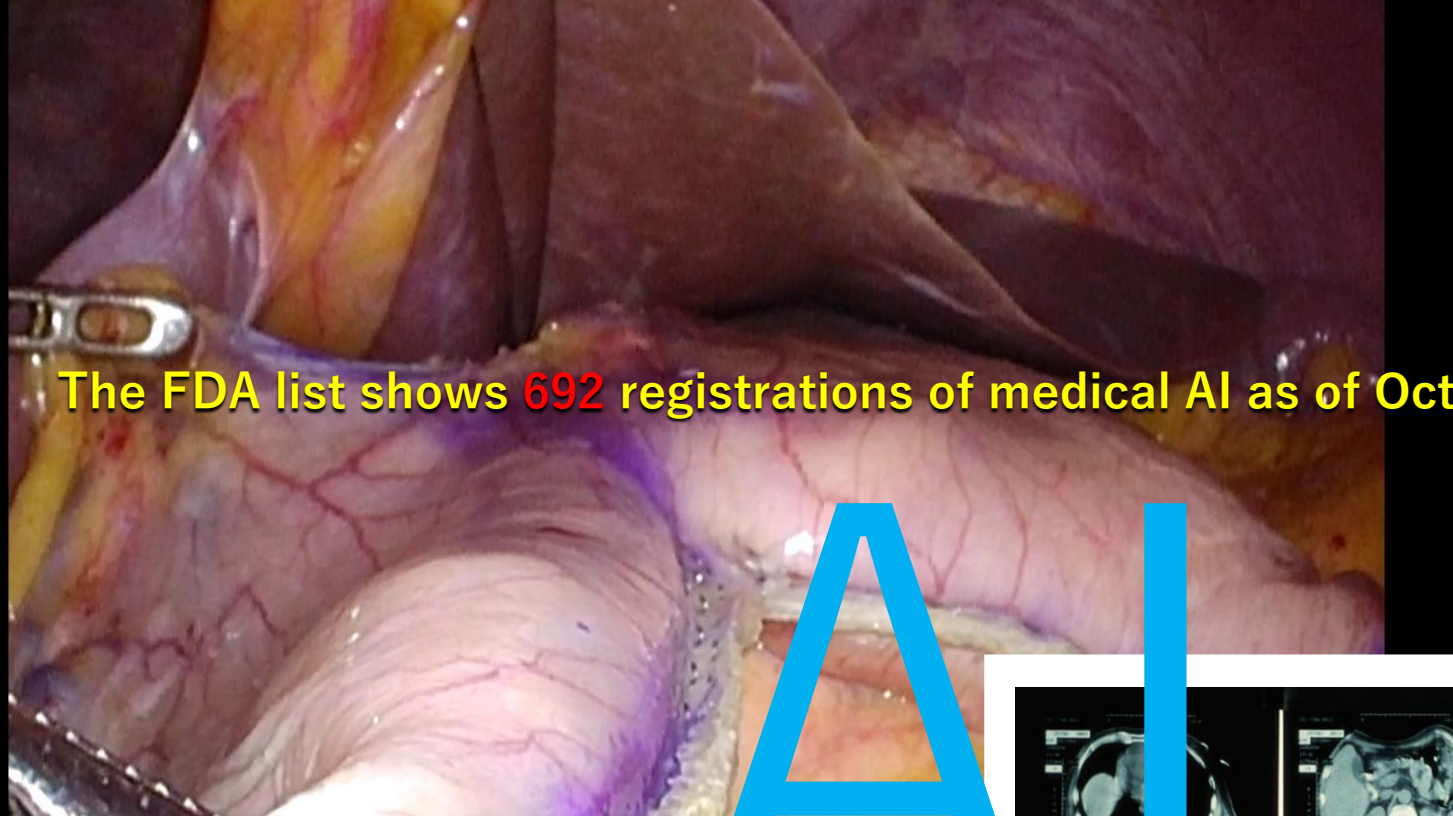


Is Home Care
Better Than
Hospital Care?



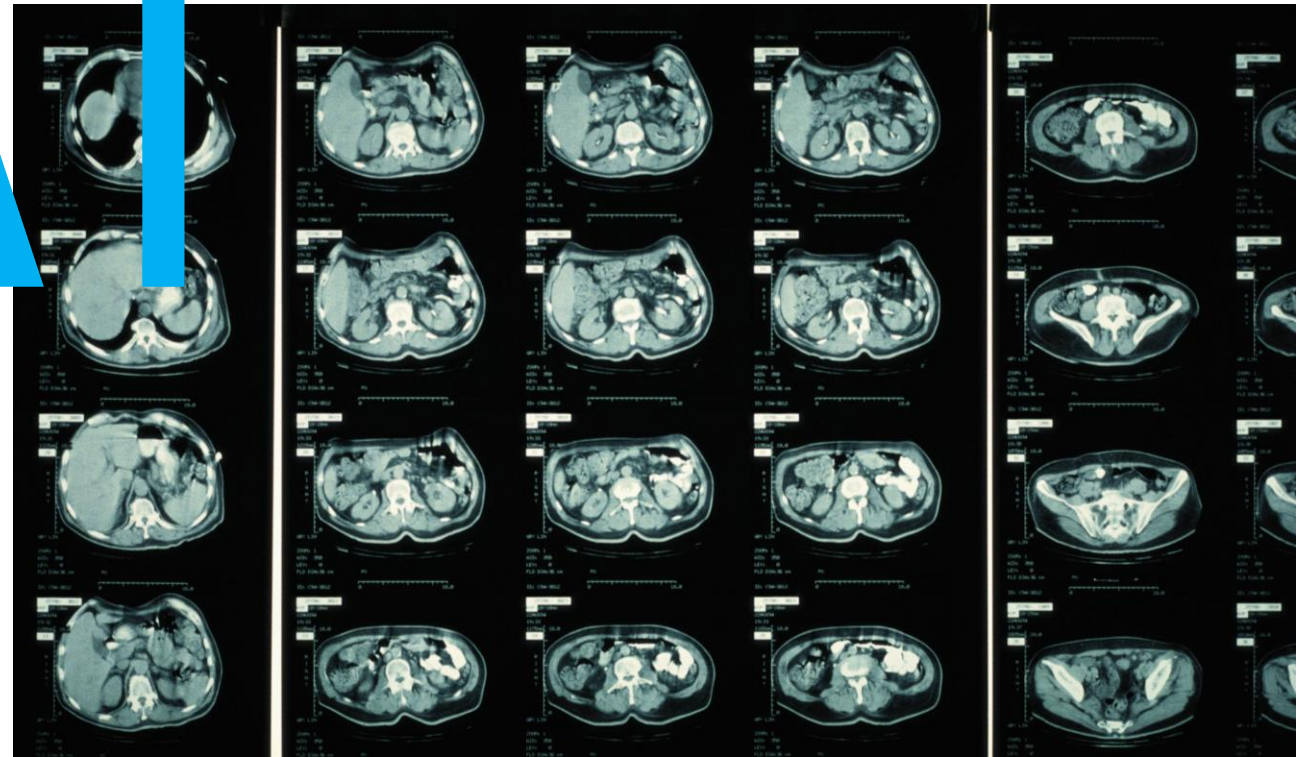
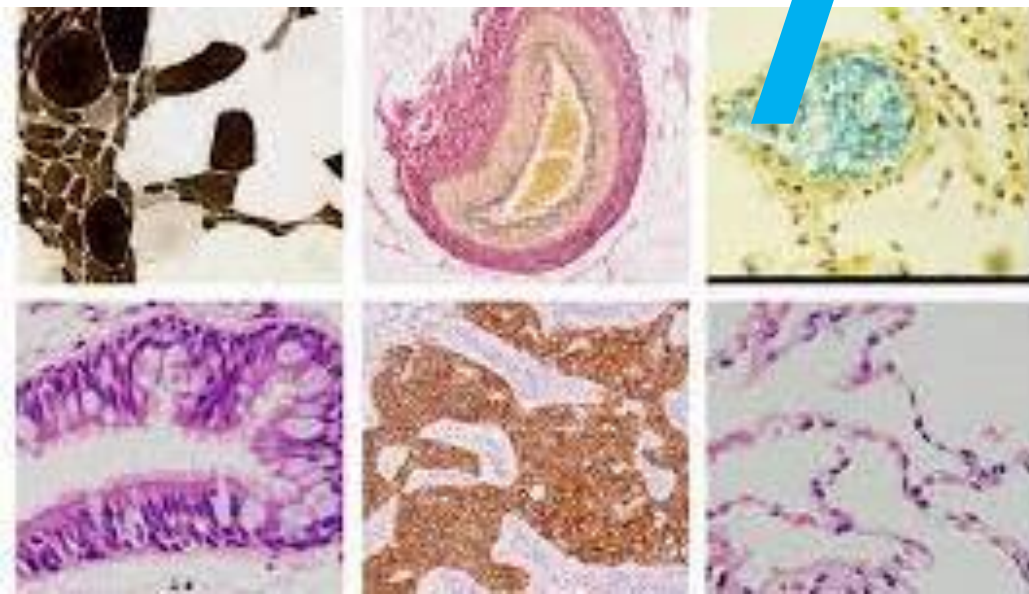






The FDA list shows 692 registrations of medical AI as of October 19, 2023.

AI



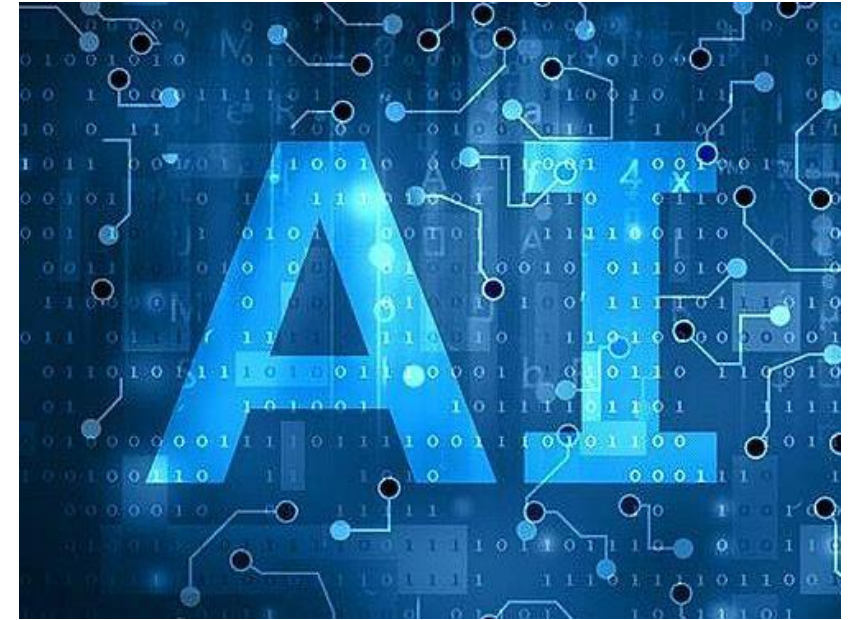
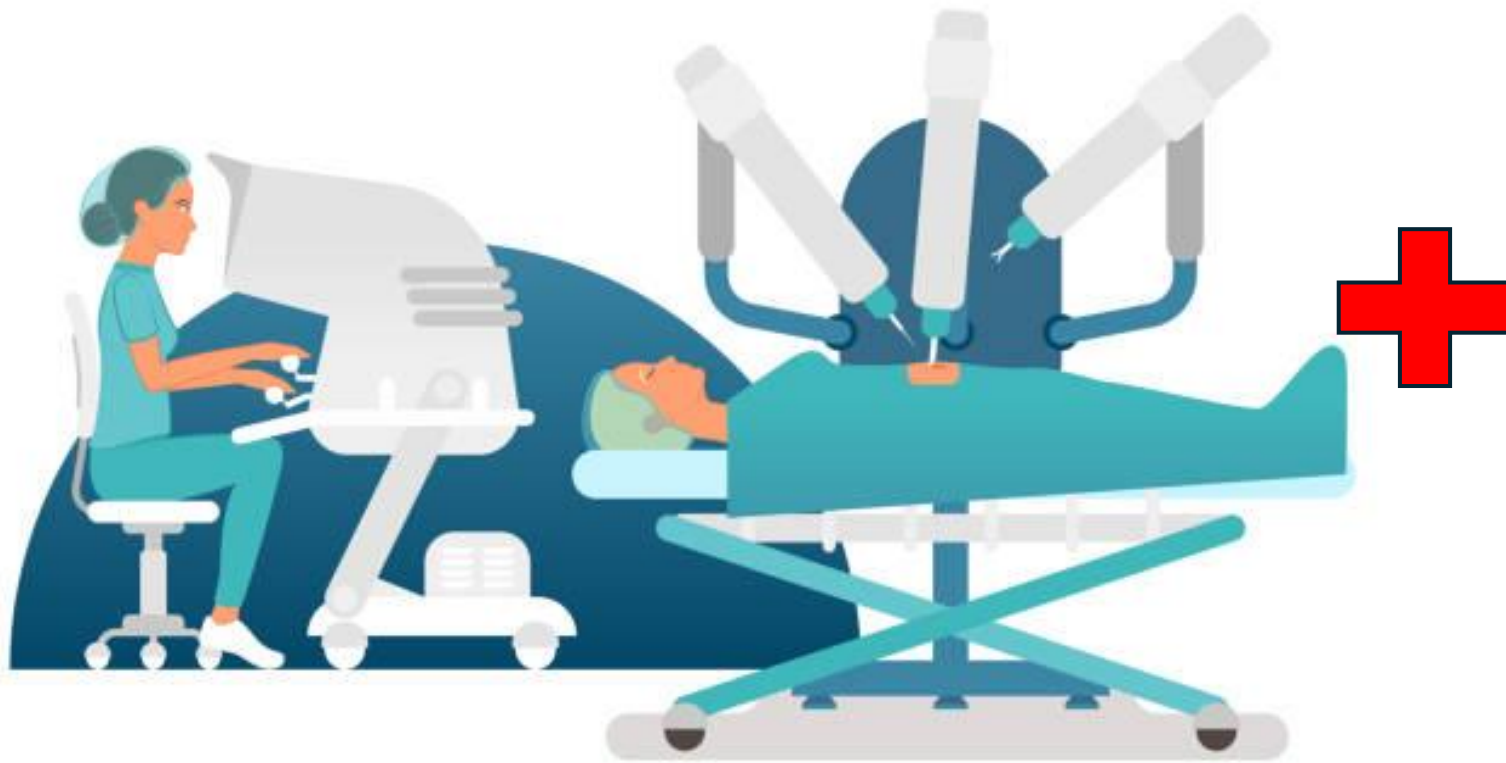


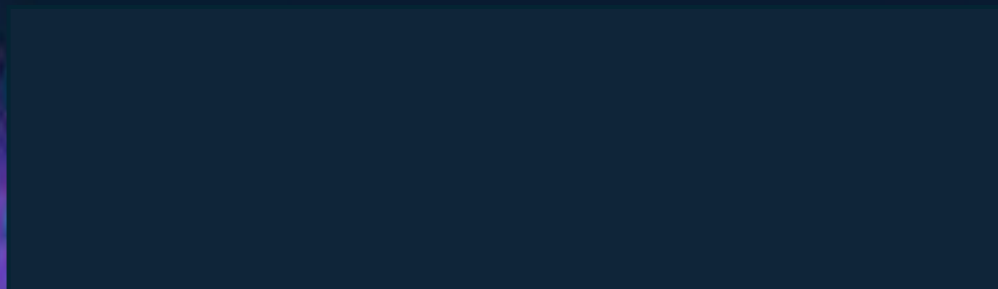
“Taxi without Taxi Driver”

Waymo’s robotaxis are now available to tens of thousands of people across all of San Francisco



ROBOTIC SURGERY





VR, AR AND THE FUTURE OF GAMING





100
FEDERAL RESERVE NOTE
LB 88529953 N
B2



100
FEDERAL
LB 888
B2

Janet L. Yellen
Secretary of the Treasury
Treasury of the United States

Janet L. Yellen
Secretary of the Treasury
Treasury of the United States

ONE HUNDRED DOLLARS
UNITED STATES OF AMERICA
THIS NOTE IS LEGAL TENDER
FOR ALL DEBTS, PUBLIC AND PRIVATE
July 4, 1776



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LB 88529953 N

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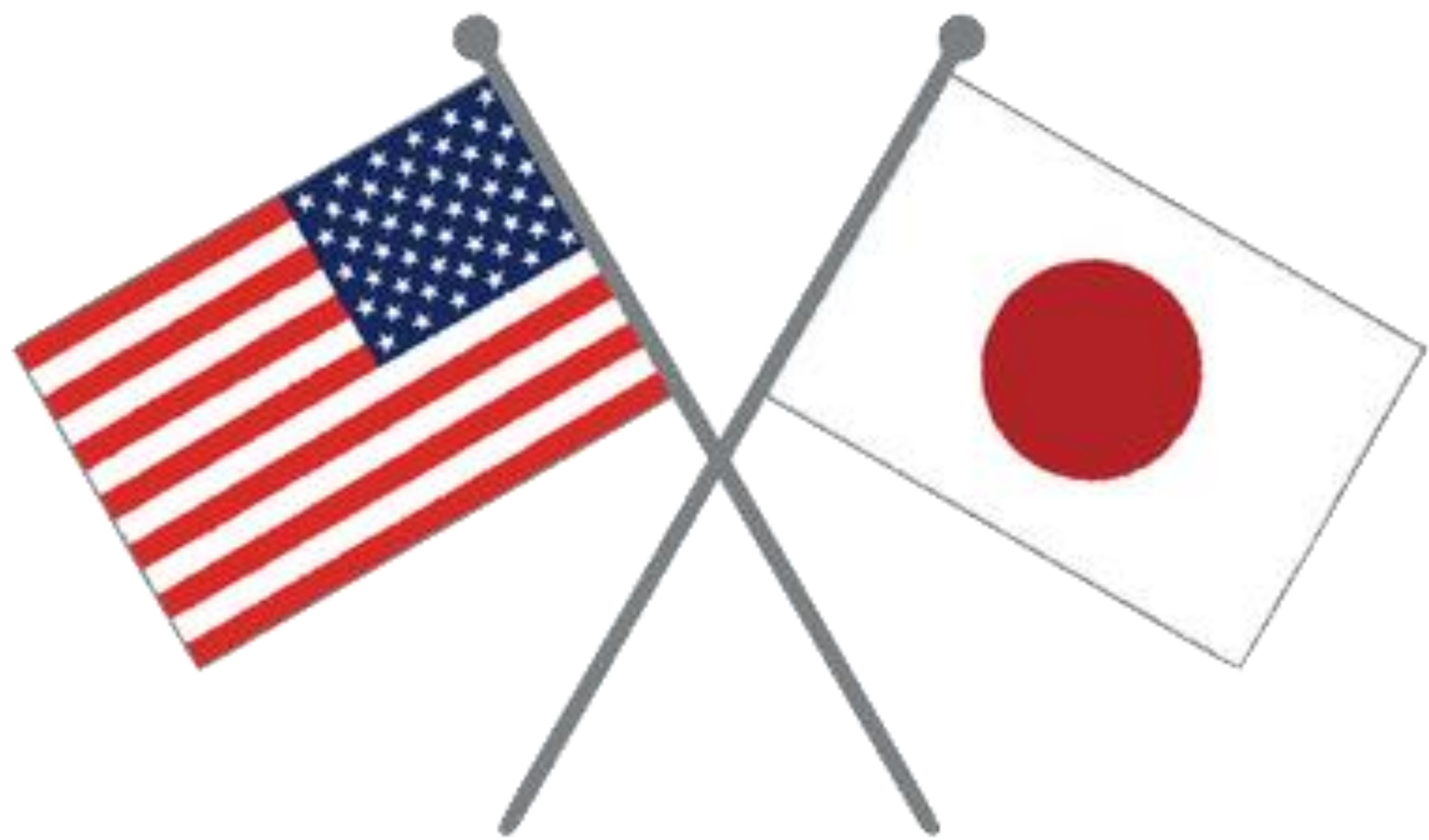
VALUE BASED CARE





A close-up photograph of a computer keyboard. The central focus is a large, rectangular orange key with rounded corners, featuring the word "Optimize" in a white, sans-serif font. The key is slightly raised above the other keys. Surrounding it are several white keys, also with rounded corners, set against a dark grey or black keyboard base. The lighting is soft, creating subtle shadows and highlights on the keys' surfaces.

Optimize



A wide-angle photograph of the Stanford University Main Quad. The central focus is the redwood building, a large, historic structure with multiple gables, arched windows, and a central entrance. The building is surrounded by a well-maintained green lawn, with palm trees and other tropical plants in the foreground. The sky is clear and blue.

Thank you very much

for “the patients!”

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