



CDRH Center for Devices and Radiological Health



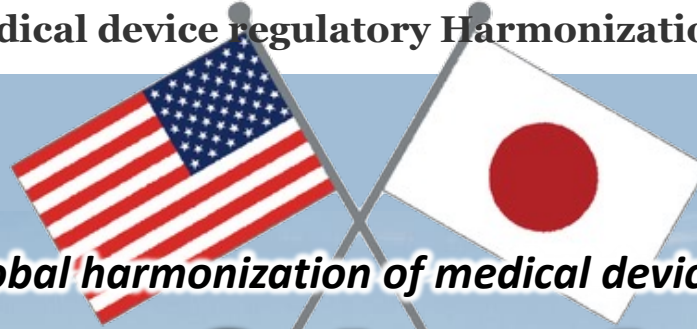
US-JAPAN HBD EAST Think Tank Meeting 2023

～日米産官学による医療機器規制調和会議～



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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Faculty of Japan Reach, CARE (Center for Asian Health Research and Education) , Stanford University

Chief Medical Officer, MedVenture Partners, Inc

COI

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



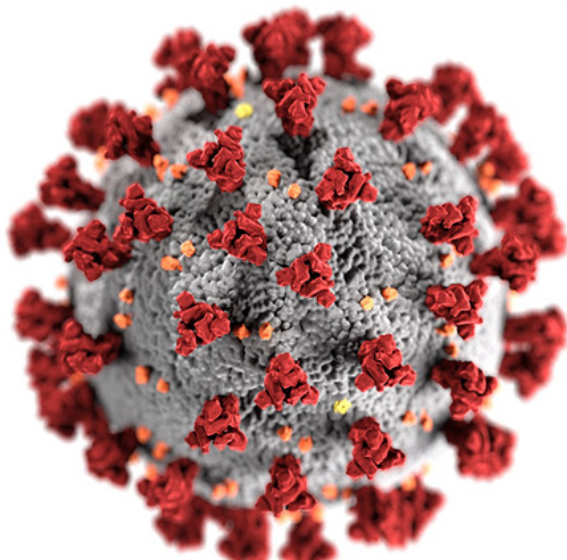
Godzilla



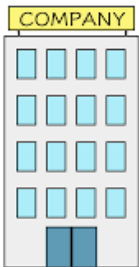
MecaGodzilla

2020

2023



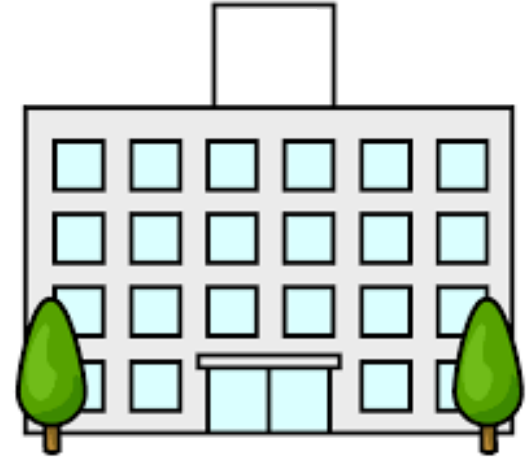
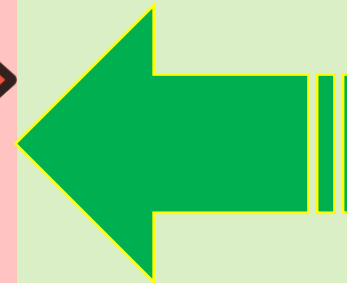
Pandemic



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



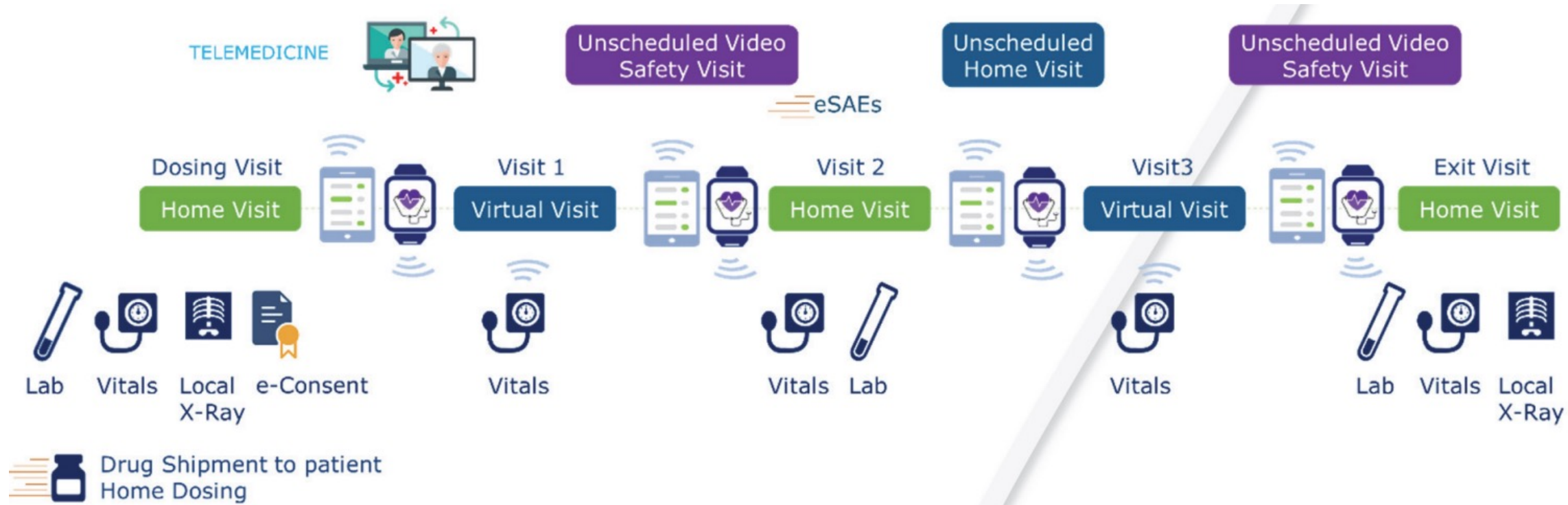
Hybrid Clinical Trial

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



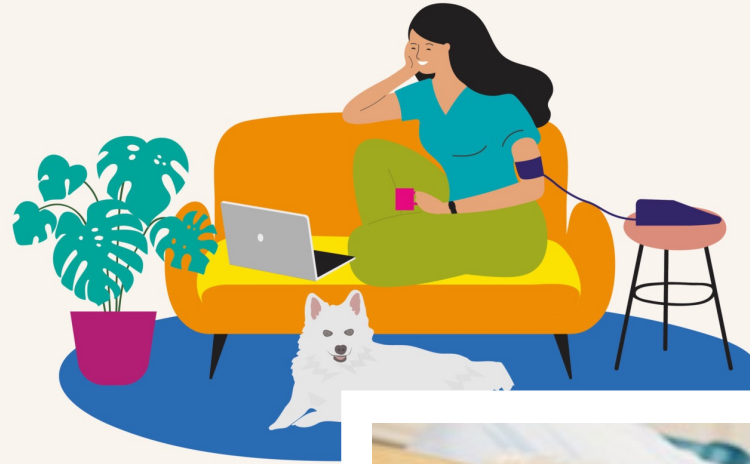
Source: SCDM [Short Brief Decentralized Trials](#)



The care of hospital, the comfort of home



Greater Manchester
Integrated Care



Find out more: gmhospitalathome.co.uk



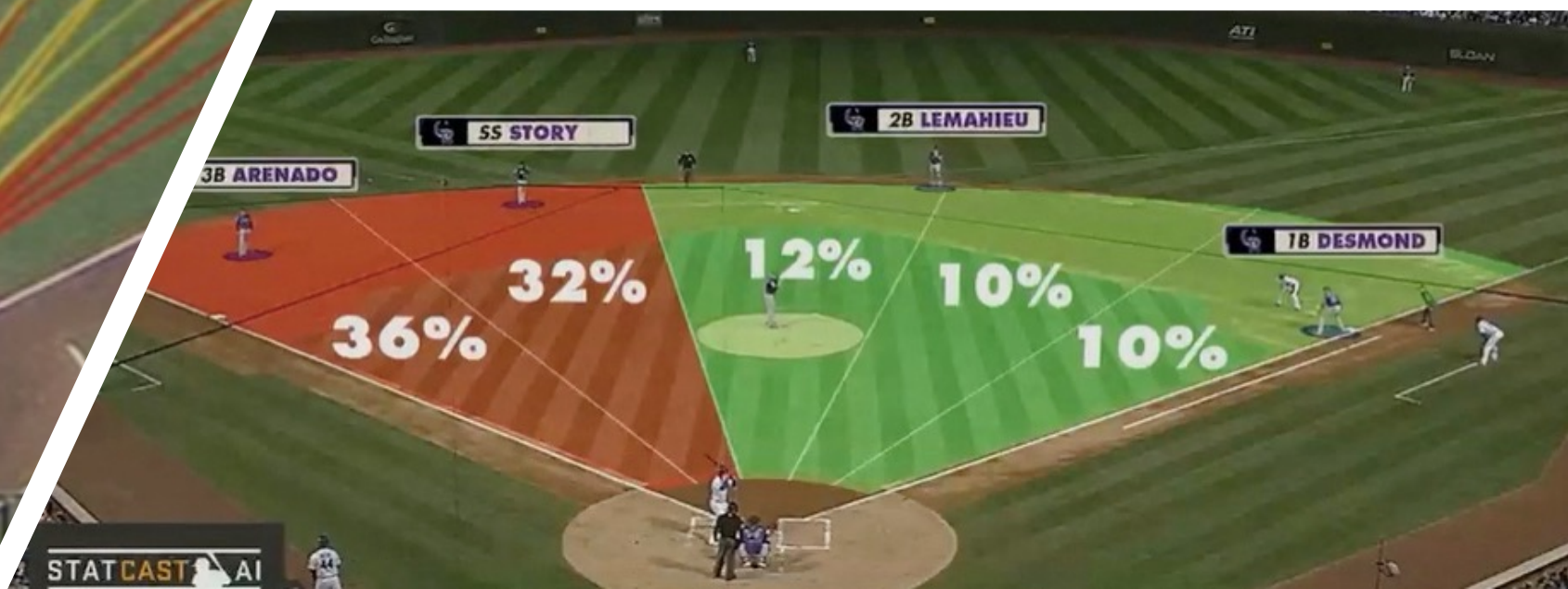
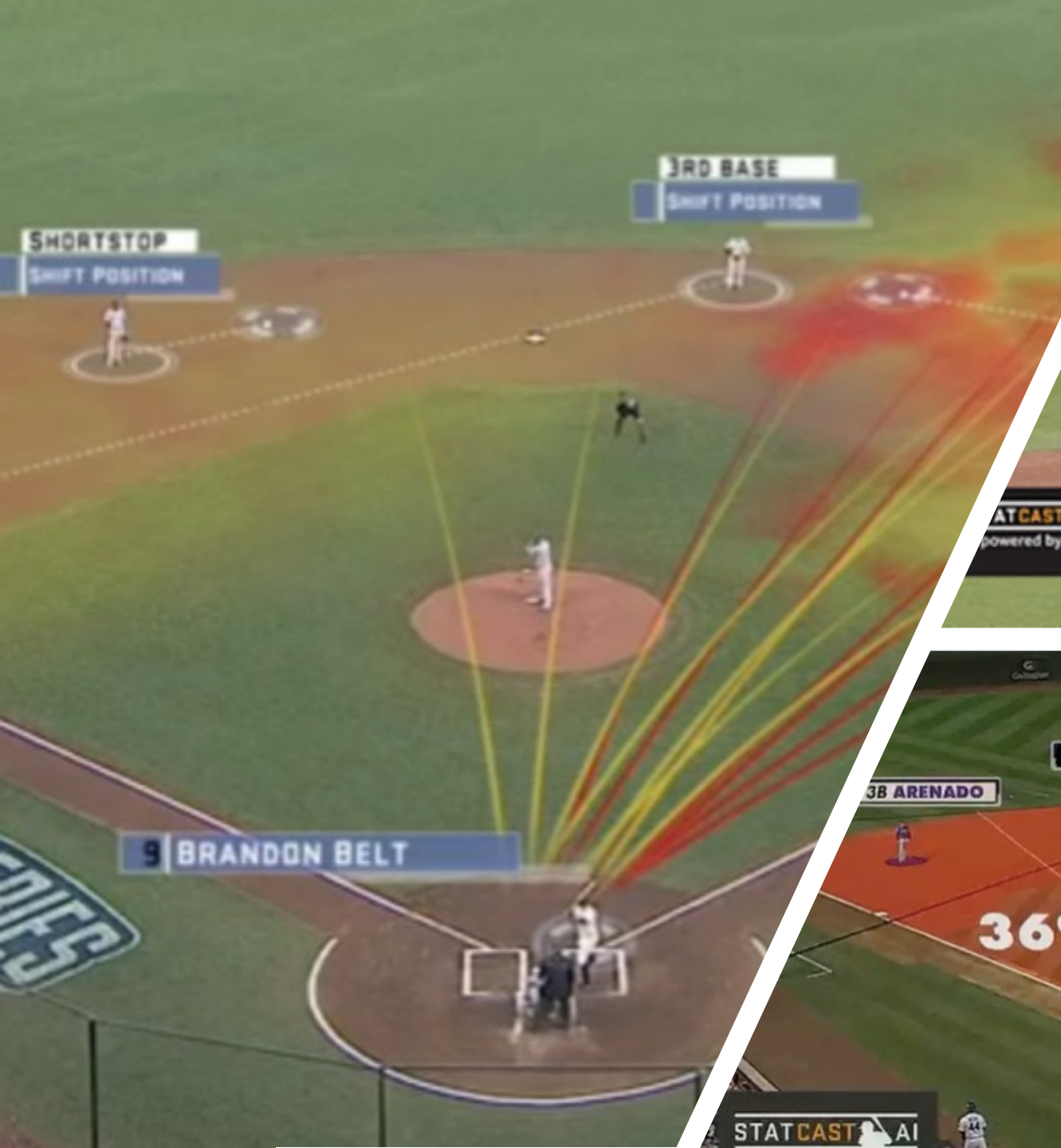
CMS Expanding to
Cover At-Home
Acute Care to Patients

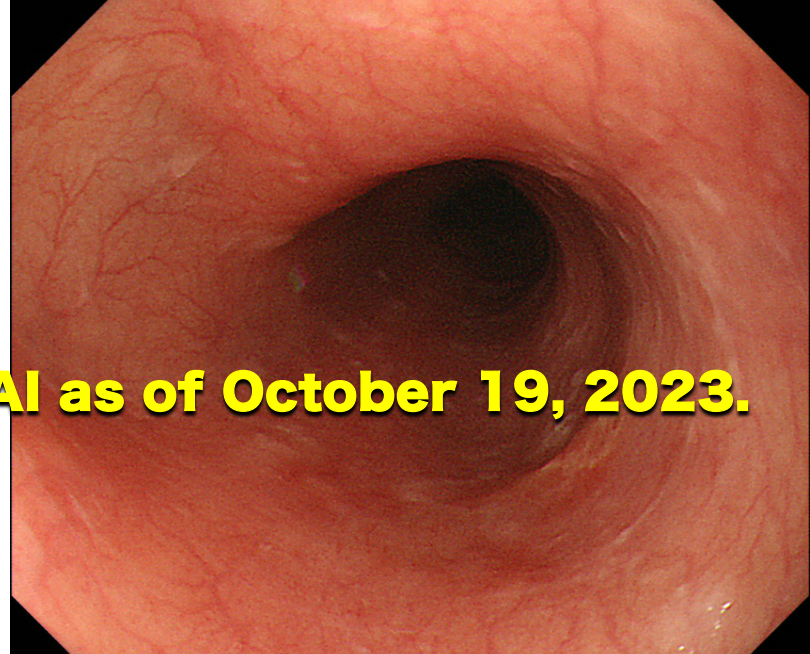
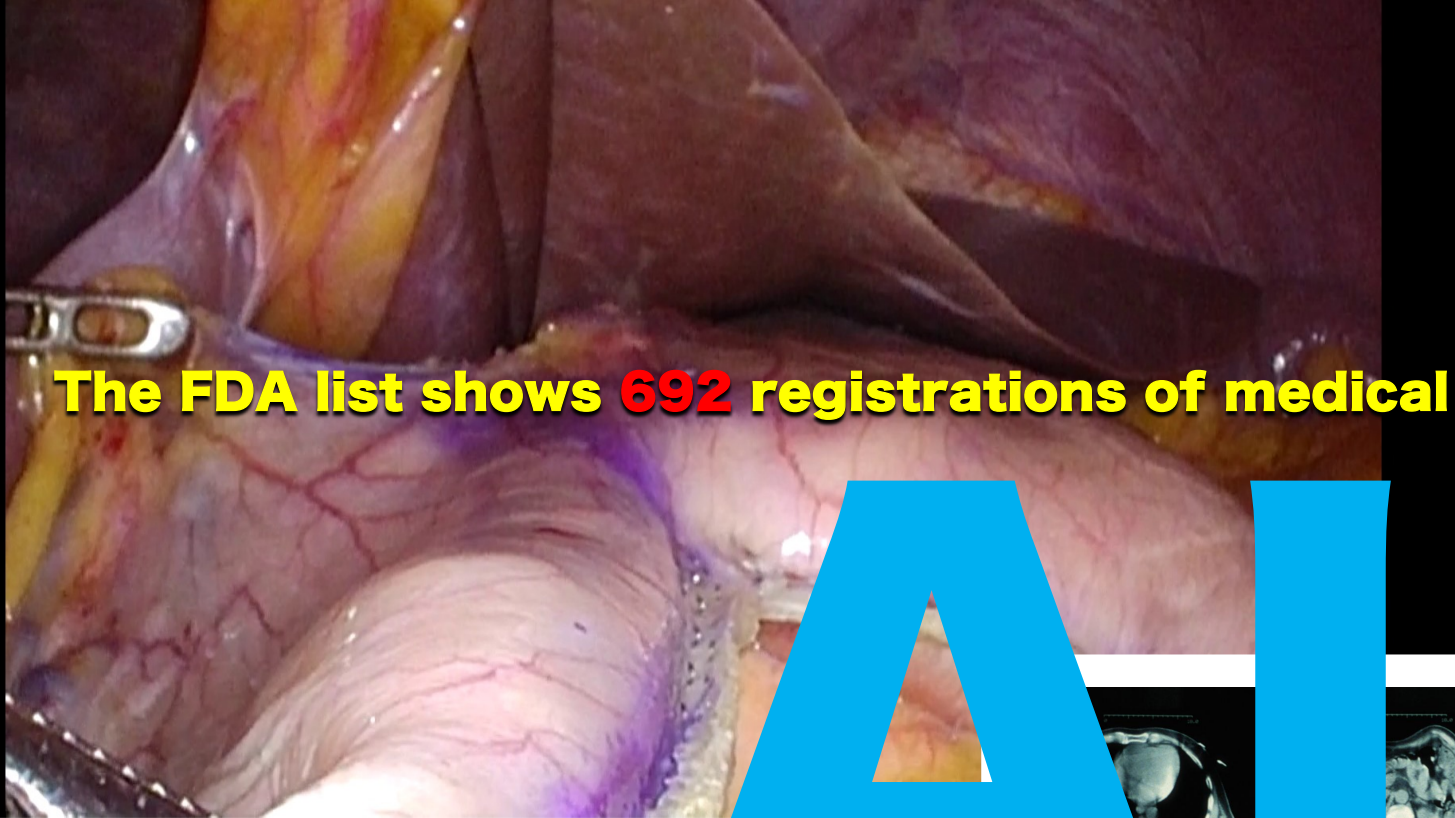


Is Home Care
Better Than
Hospital Care?

data

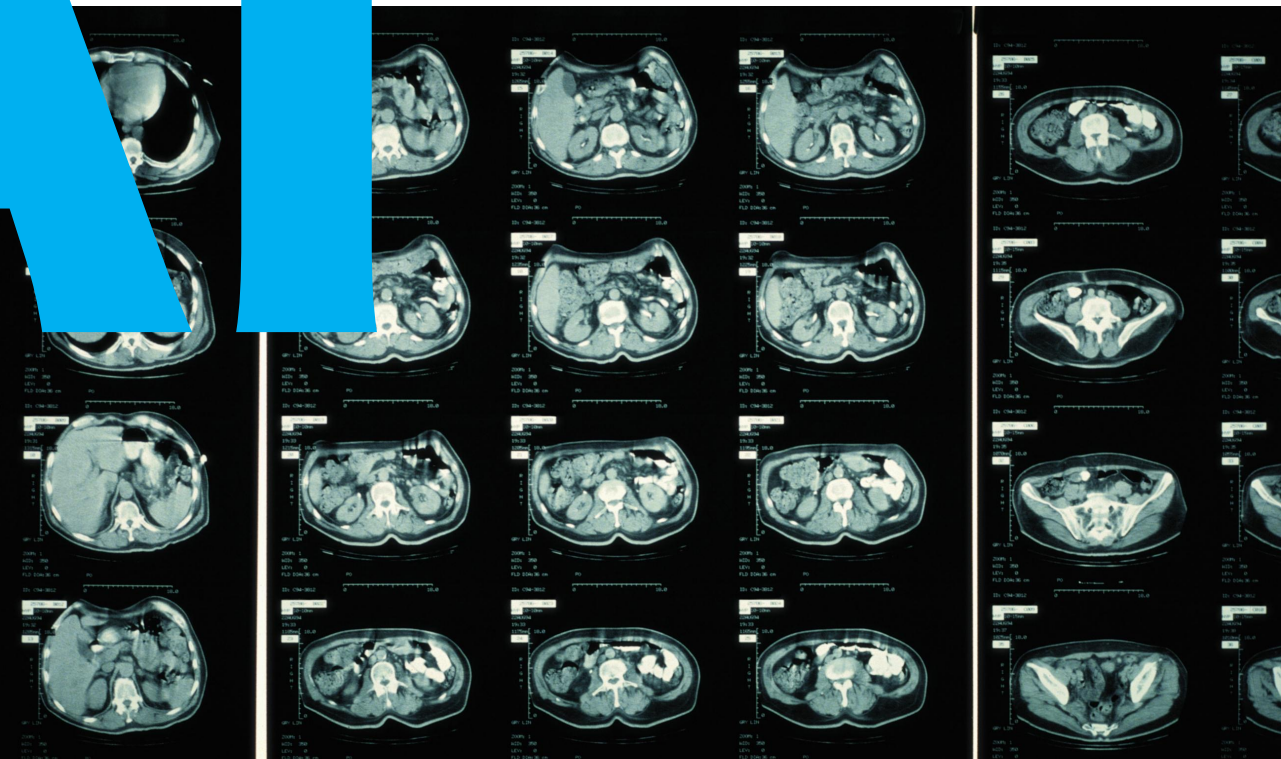
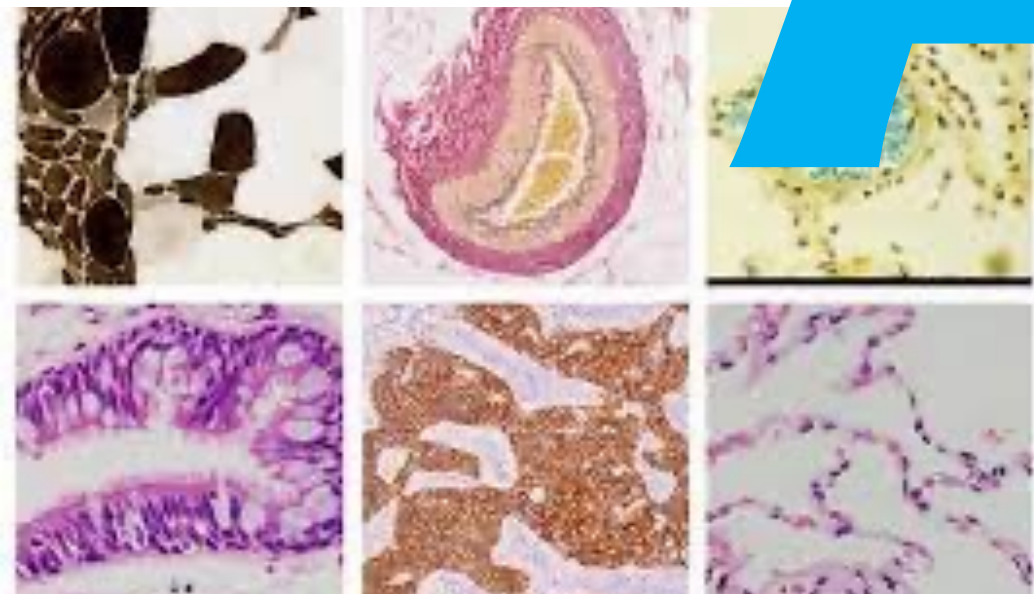






The FDA list shows **692** registrations of medical AI as of October 19, 2023.

AI



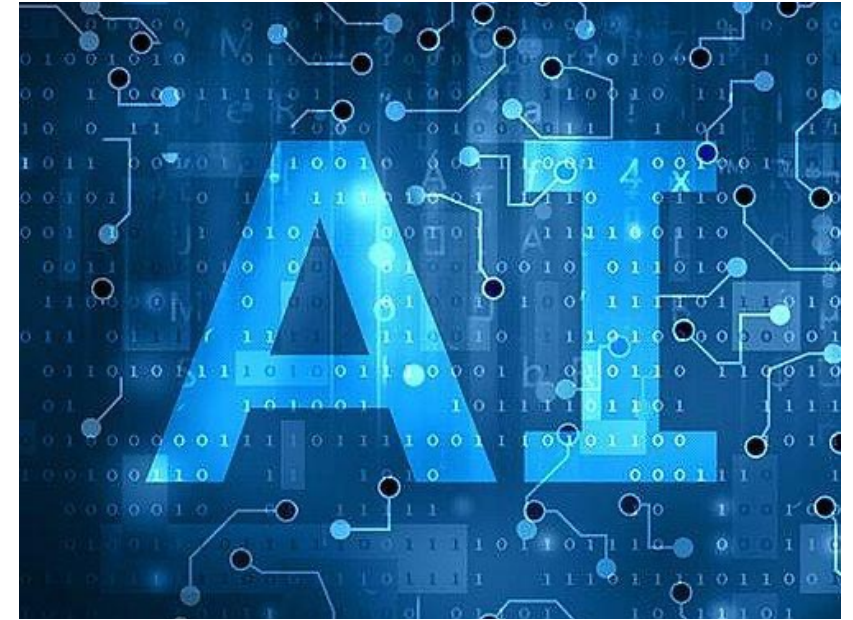
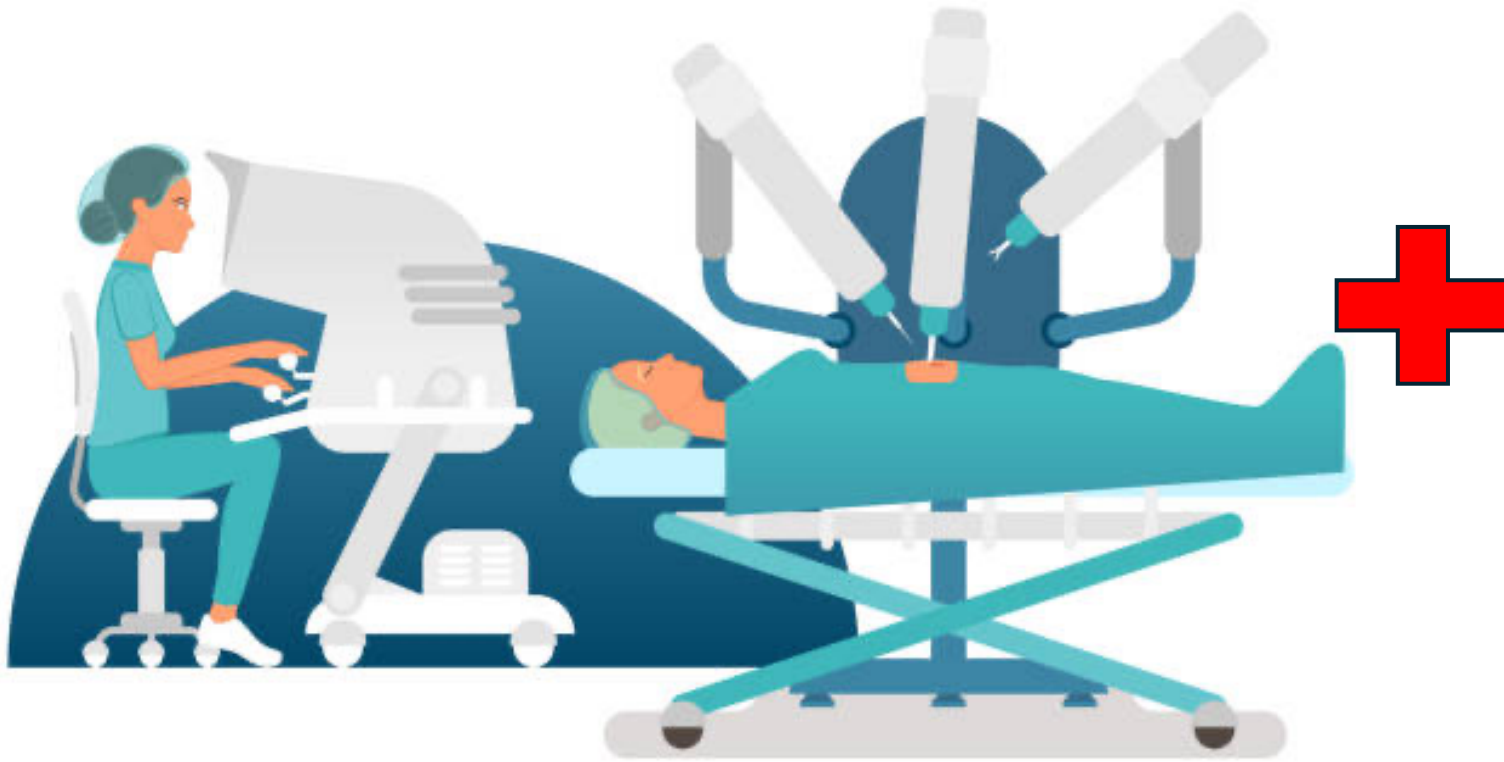


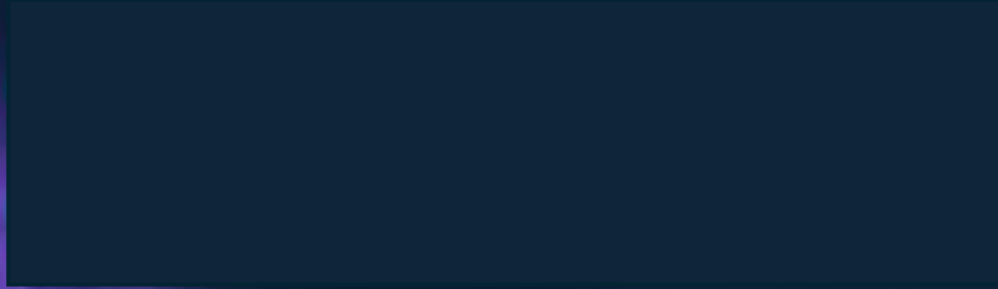
“Taxi without Taxi Driver”

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





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FEDERAL RESERVE NOTE
LB 88529953 N
B2



Janet L. Yellen
Secretary of the Treasury
Laura M. Berkowitz
Treasurer of the United States



100
FEDERAL
LB 88
B2

Janet L. Yellen
Secretary of the Treasury
Laura M. Berkowitz
Treasurer of the United States

ONE HUNDRED DOLLARS
DRAWN IN COA
July 4, 1776
THIS NOTE IS LEGAL TENDER
FOR ALL DEBTS, PUBLIC AND PRIVATE

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LB 88529953 N

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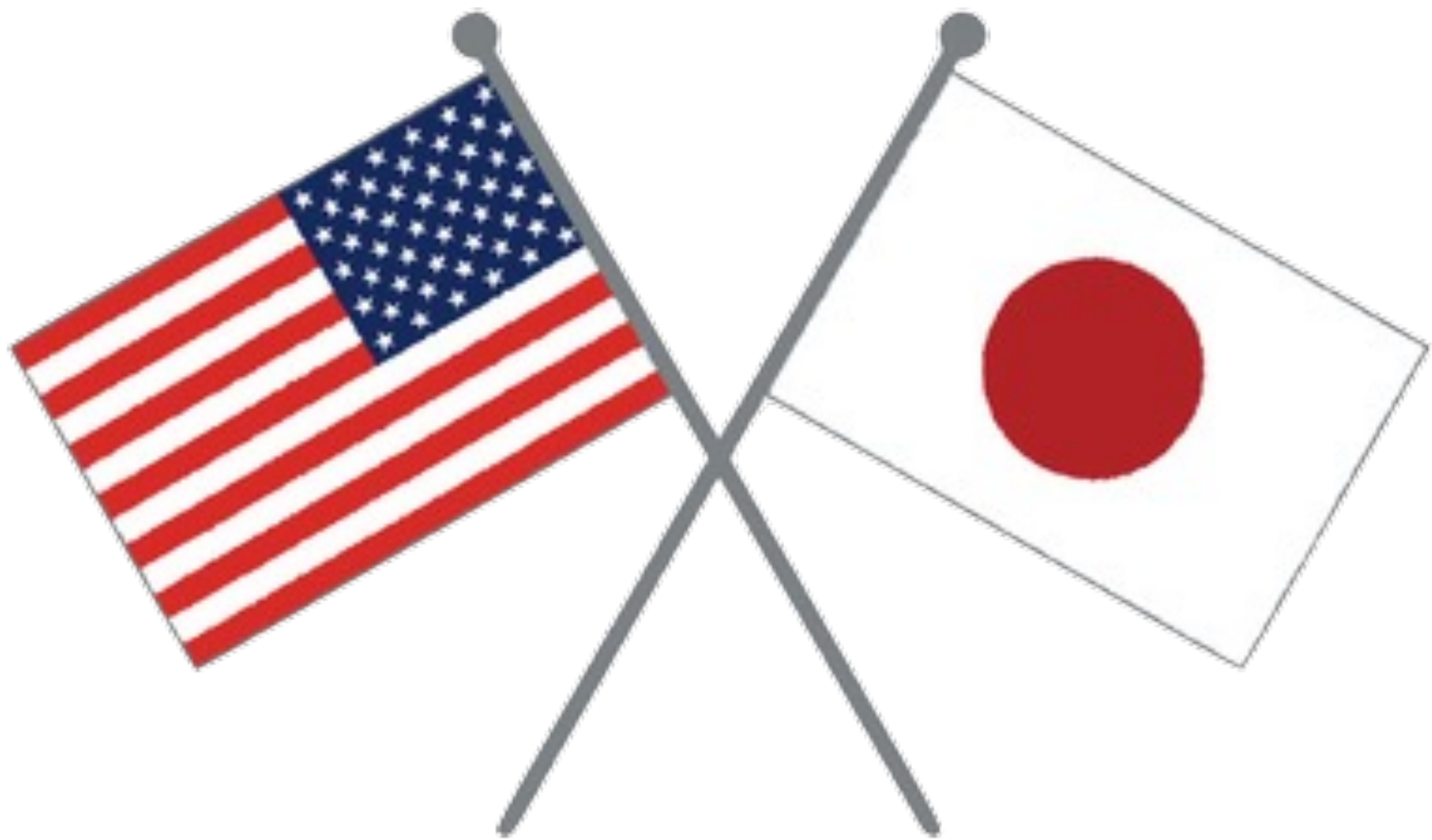
VALUE BASED CARE





A close-up photograph of a computer keyboard. The central focus is a single, large, rectangular key with a vibrant orange color. The word "Optimize" is printed on this key in a clean, white, sans-serif font, oriented diagonally from the bottom-left to the top-right. The key is surrounded by other keys, which are white and slightly out of focus. The lighting is soft, highlighting the texture of the key and the surrounding keys.

Optimize



A wide-angle photograph of the Stanford University Main Quad. The central focus is the redwood Gothic Main Building, a large stone structure with a prominent central tower and arched windows. The building is flanked by two long, two-story wings with red-tiled roofs and arched walkways. In the foreground, a large, well-maintained green lawn is bisected by a paved walkway. Several palm trees are scattered throughout the scene, particularly in the foreground and along the sides. The background shows a lush green hillside under a clear sky. The overall atmosphere is bright and sunny.

Thank you very much

for "the patients!"

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