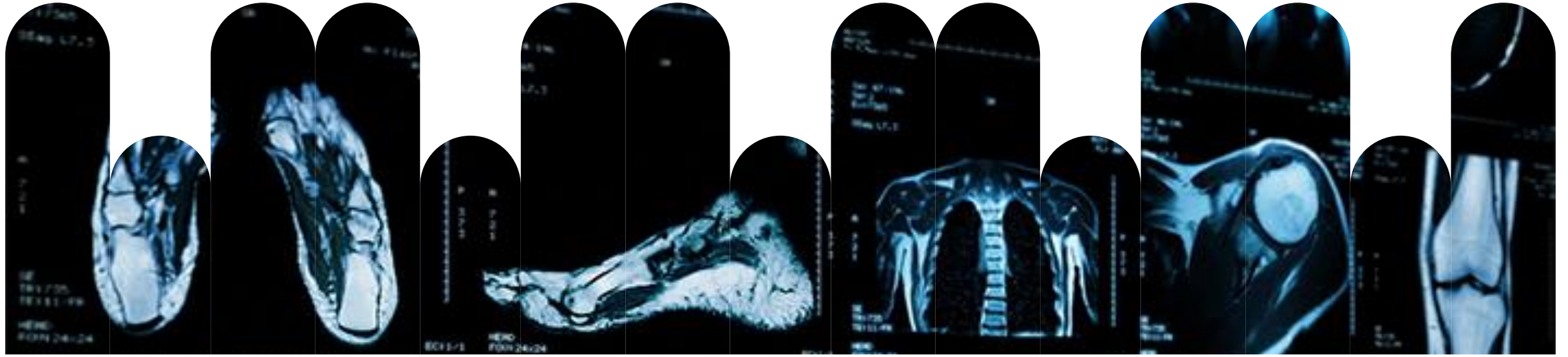
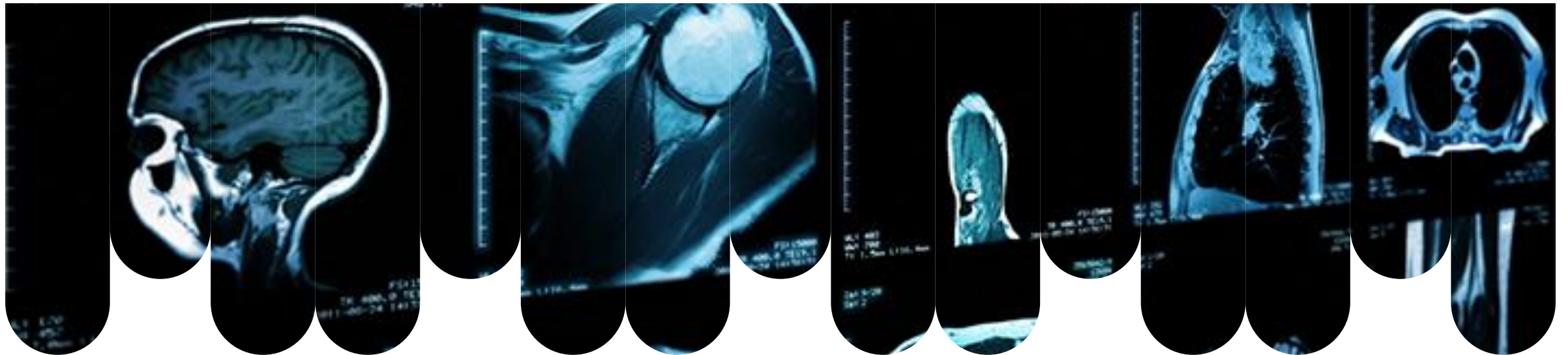


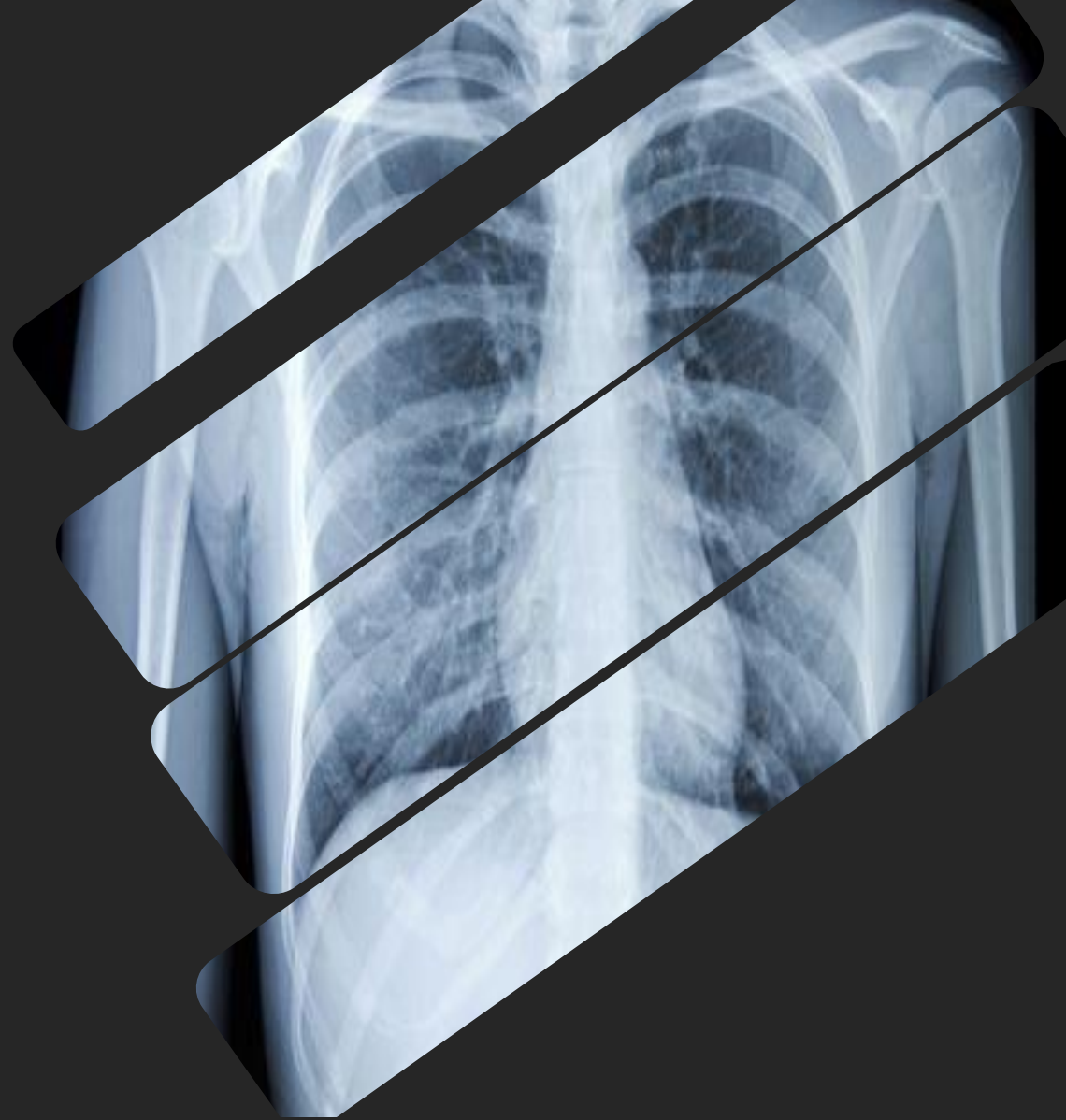


ROLE OF X-RAY AND CT IN COVID-19



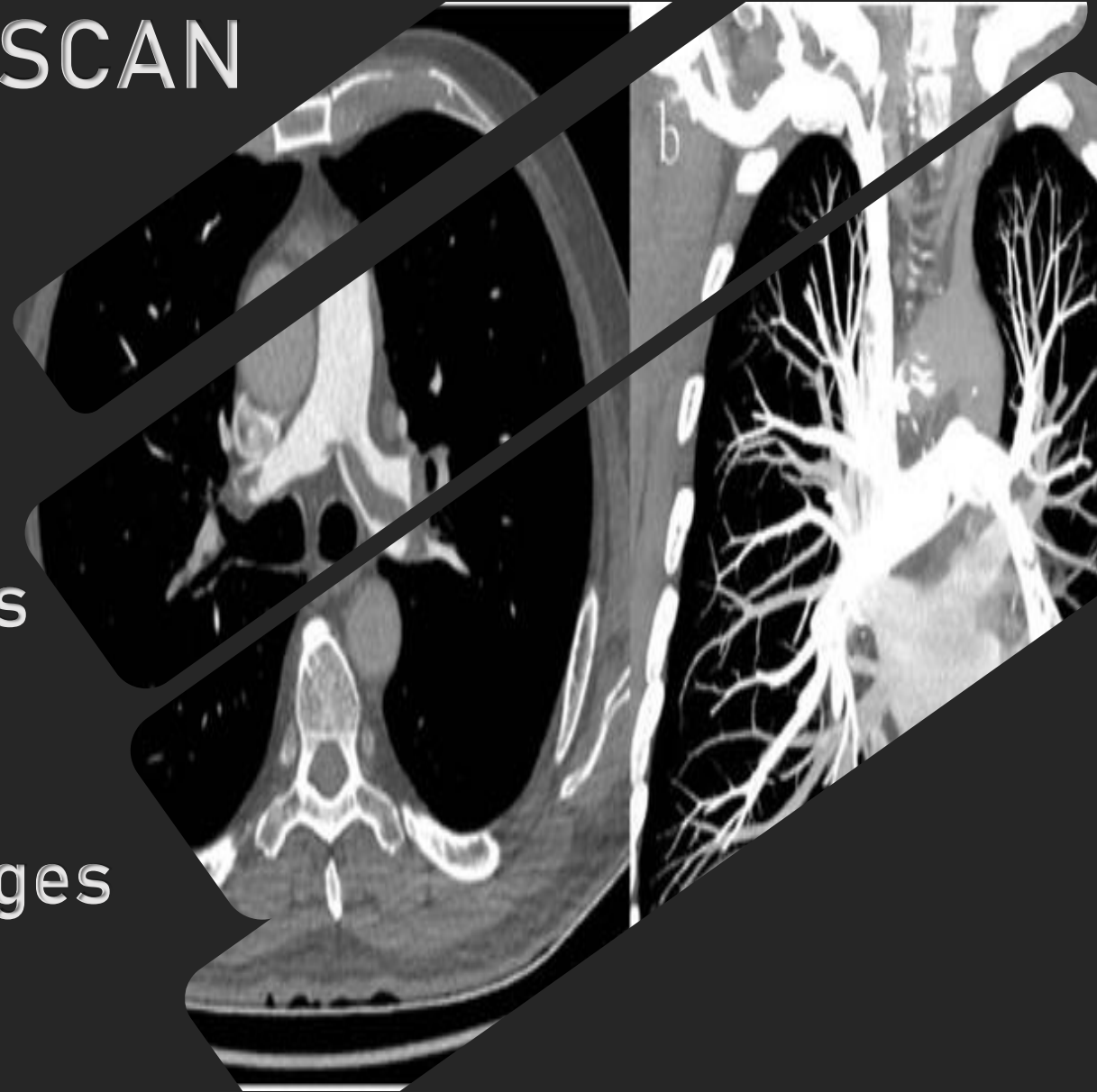
X-RAY

An electromagnetic wave of high energy & short wavelength, which is able to pass through many materials opaque to light



COMPUTED TOMOGRAPHY SCAN

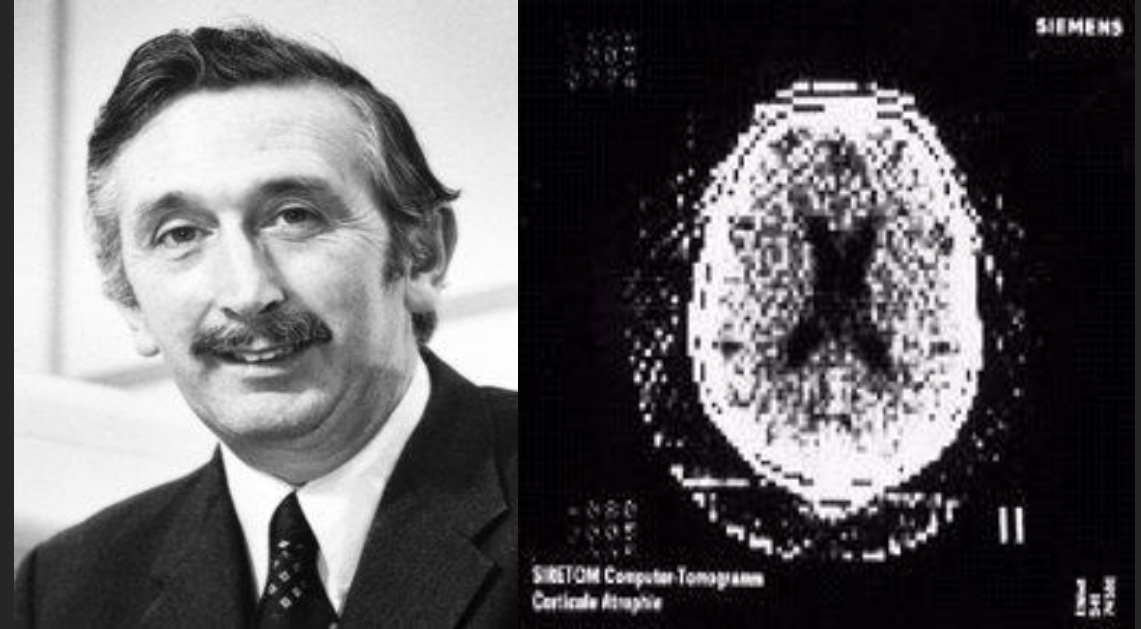
CT is a medical imaging procedure that uses computer processed combinations of many x-ray measurements taken from different angles to produce cross sectional images



HISTORY OF X-RAY AND CT



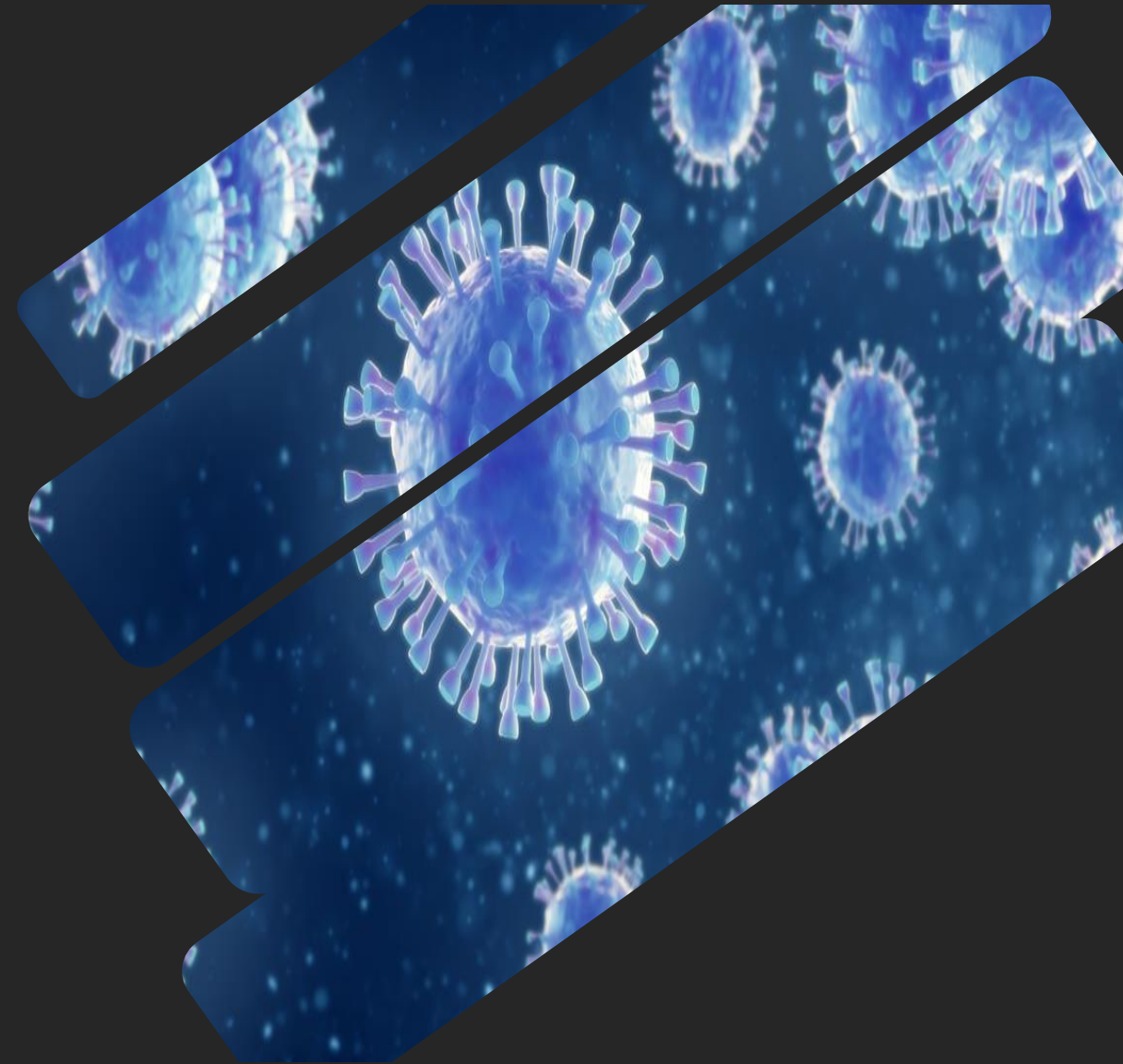
WILHELM ROENTGEN- FATHER
OF RADIOGRAPHY
YEAR OF INVENTION -1895



GODFREY HOUNSEFIELD
YEAR OF INVENTION-1972

COVID-19

Coronavirus disease 2019 is defined as illness caused by a novel coronavirus now called severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2); formerly called 2019-nCoV), which was first identified amid an outbreak of respiratory illness cases in Wuhan City, Hubei Province, China



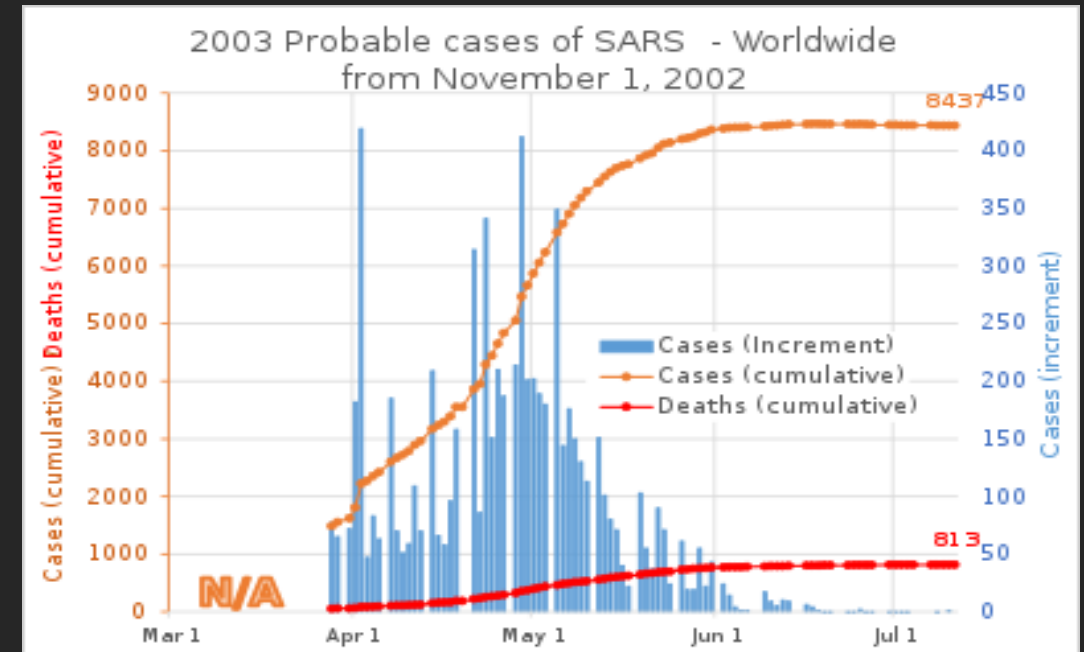
HISTORY OF CORONA

- In 1931 M.C Hawn and Arthur Schalk discovered a novel respiratory infection of chickens in North Dakota.
- After six years Fred Beaudette and Charles Hudson isolated and cultivated the IBV which was responsible for the disease. Two more coronaviruses- mouse hepatitis virus (MHV) and transmissible gastroenteritis virus (TGV) emerged and were successfully isolated.
- In the 1960's first corona virus in humans were discovered- B814 and 229E.
- . Many human coronavirus have been identified since 2003- SARS-CoV in 2003, HCov NL63 in 2004, HCov HKU1 in 2005, MERS-CoV in 2012 and SARS-CoV-2 in 2019.



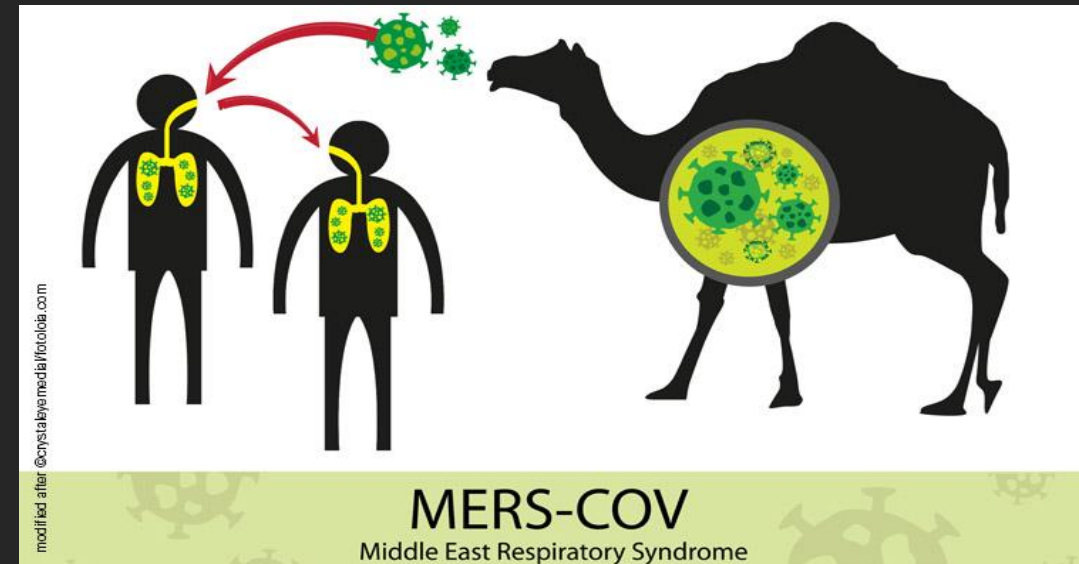
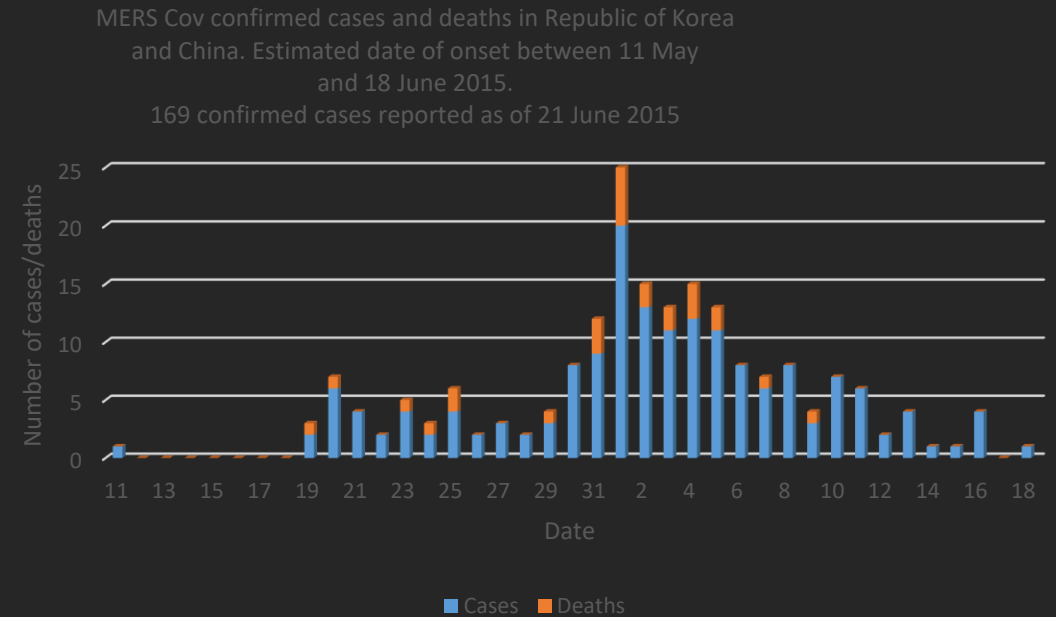
SEVERE ACUTE RESPIRATORY SYNDROME (SARS)

- SARS-CoV is the virus responsible for causing SARS.
- SARS-CoV has a reproductive number of 0.3–4.1 and can be easily transmitted through respiratory droplets when exhaled by an infected person while coughing or sneezing.
- SARS was recognized in March 2003 as a threat to the world, and appeared in Southern China in November 2002. It was spread across 5 continents and 33 countries. 8347 people were infected with SARS and 813 died.
- The reported rate of mortality is 9.6%.



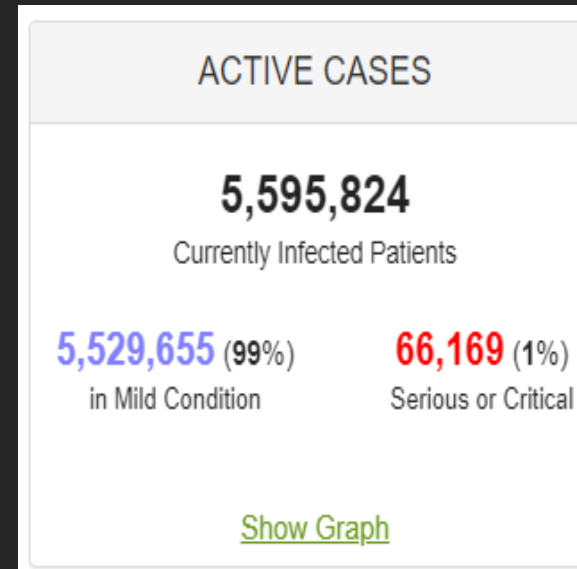
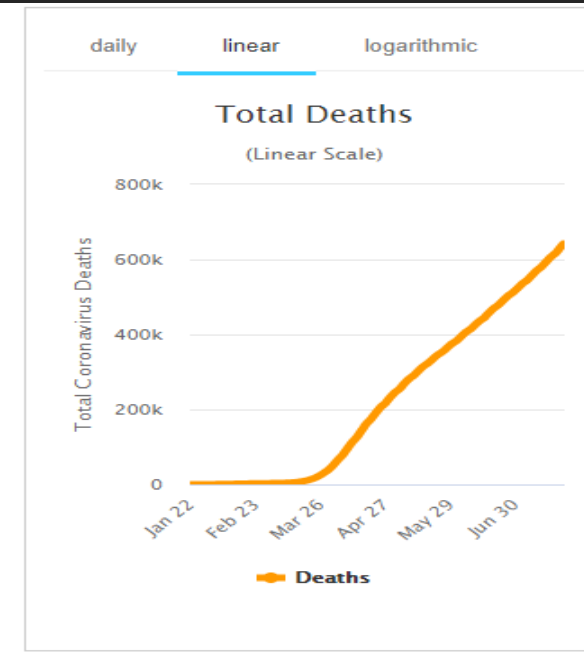
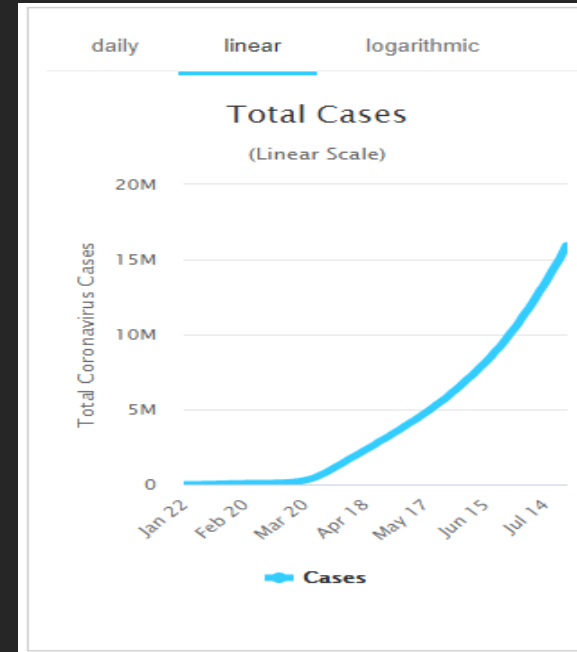
MIDDLE EAST RESPIRATORY SYNDROME (MERS)

- MERS-CoV was the virus responsible for causing MERS.
- MERS can be easily transmitted from person to person under close contact or while providing care to infected patient without protection with a reproductive number of 0.3–1.3.
- The fatality rate for MERS is 34.3%.
- MERS was declared as an epidemic in the middle-east and WHO reported 1583 cases with 566 death.



CORONAVIRUS DISEASE 2019(COVID-19)

- Covid-19 is caused by the virus SARS-CoV-2.
- SARS-CoV-2 spreads from person to person under close contact.
- The first outbreak was identified in Wuhan, China in the month of December 2019. Covid-19 was declared as a pandemic by the WHO on 11th March 2020.
- The signs and symptoms of Covid-19 were—cough, loss of appetite, shortness of breath, joint pain, headache, chest pain and muscle pain. Severe patients develop pneumonia.



COMPARISON OF COVID-19 WITH PREVIOUS SEVERE CORONAVIRUS

CHARACTERISTICS AND OTHER FACTORS	SARS	MERS	COVID-19
Total Cases	8096	2519	16,061,065
Total Deaths	774	866	644,995
Person to person transmission	Yes (droplet, contact)	Yes (droplet, contact)	Yes (droplet, contact)
Infection control risk	High	High	High
Years active & year identified	2002-2004 (2002 identified)	2012-present (2012 identified)	2019-present(2019)
Family	Coronaviridae	Coronaviridae	Coronaviridae
Genome	RNA	RNA	RNA
Endemic/Pandemic Location	China	Middle East	China
Reservoir	Bats, palm civet	Bats, camel	Bats
Incubation period	2-7 days	2-14 days	2-14 days
Reproduction number	0.3-4.1	0.3-1.3	5.7
Mortality rate	9.6%	34.4%	4.01%
Clinical therapy	Supportive	Supportive	Supportive

RATIONALE



“The coronavirus disease (COVID-19) presents itself as a highly communicable pathogenic viral infection caused by SARS-CoV-2. The primary region of infection in Covid-19 are the lungs. Pneumonia and ARDS were the reason for death in severe cases. Diagnostic plays a vital role in identifying the cases who have been infected. X-rays and CT scan provides the images of the human lungs with high sensitivity at ease and consumes less time. The image characteristics of the Covid-19 positive patients help us to study the condition of the patient along with time and when deep learning models are combined with X-rays and CT scan we get accurate results.

”

RESEARCH QUESTION

To study the role of x-rays and computed tomography in Covid-19?

RESEARCH OBJECTIVES

- To understand the image characteristics of novel coronavirus in x-rays.
- To understand the image characteristics of novel coronavirus in computed tomography
- Does deep learning help in deriving more accurate results or not.

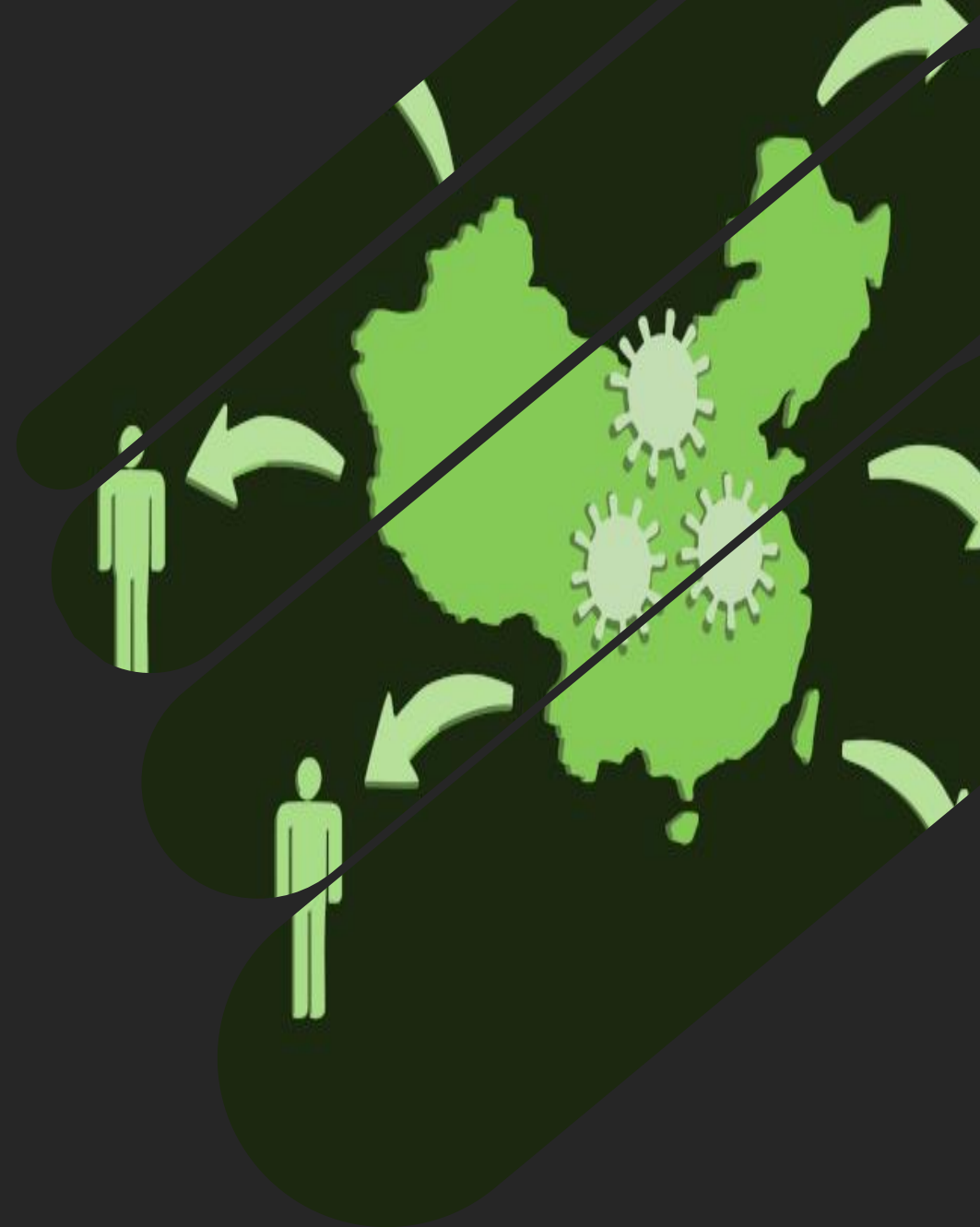
METHODOLOGY

The report is based on the descriptive secondary research data. Previous articles regarding history of X-ray and CT scan, SARS, MERS, Covid-19 and history of coronavirus were also reviewed. Articles pertaining to imaging findings in X-ray, CT scan and the application of deep learning features to detect Covid-19

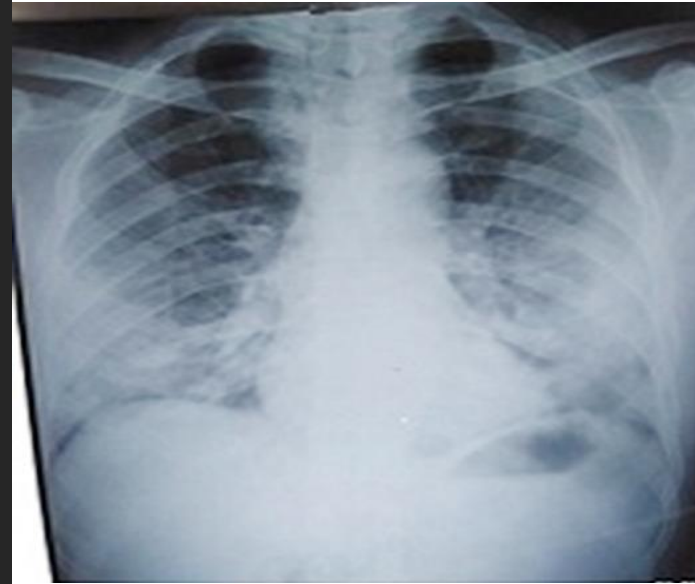


DISCUSSION

- Sars-Cov-2, MERS-Cov and Sars-Cov are part of the same family of virus i.e family of Coronaviridae.
- Sars-Cov-2 can be easily transmitted through air droplets and person to person contact so it proves to be a huge threat to global public health.
- All these virus are zoonotic virus i.e the source of infections are wild animals- bats or camels.
- Covid-19 has a lower mortality rate (5.3%) as compared to SARS (9.6%) and MERS (34.3%) but higher reproduction rate (5.7) when compared with SARS (0.3-4.1), MERS (0.3-1.3)
- Shortness of breath, cough, fever, fatigue, muscle pain were some of the common signs and symptoms of patients suffering from Covid-19, SARS or MERS.
- If the patient is older than 60 years or suffering from any comorbidity and is immunosuppressed then they have a higher chance of death.
- More than 80% of the cases in SARS and MERS showed abnormalities in their chest radiograph.
- Opacities were found in the lower lung zone along with the presence of GGO and consolidation in the lungs. Involvement in four or more lung zones and consolidation progressed 12 days after the onset of symptoms in SARS. Pleural effusion, interlobular septal thickening isolated consolidation was seen in 20-33% patients in MERS.



- Chest X-ray and portable chest X-ray are the best alternate method for testing Covid-19 patients. Portable chest X-ray gets an advantage when compared with an OPD X-ray room or CT scan room because decontamination measures cannot be followed there.
- Chest radiographs were able to depict that the peripheral region and lower lung zones were affected.
- Middle lobe involvement should be included in classical chest X-ray of Covid-19 which can help in future studies for a bigger scale.
- Chest X-ray images showed GGO, peripheral consolidation, single nodular consolidation and air bronchograms.
- Pattern of consolidation were in different shapes and sizes- in-homogenous, overlapping or patchy nodular opacity.
- Chest X-ray has a low sensitivity and differentiating between Covid-19 or other viral pneumonia is difficult based in chest X-ray.

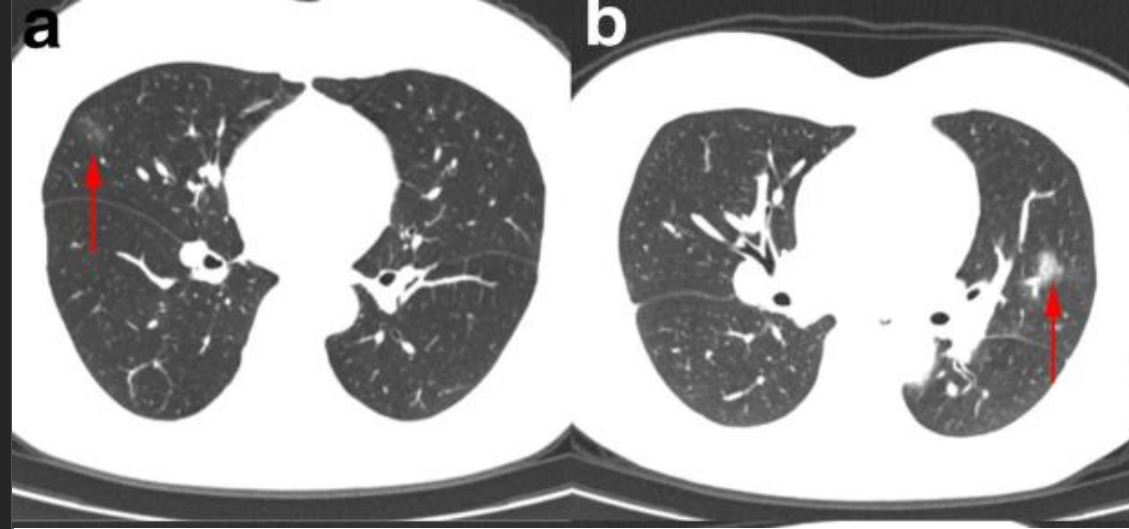


Extensive
Bilateral
peripheral
consolidation with
air bronchograms
predominantly
right side

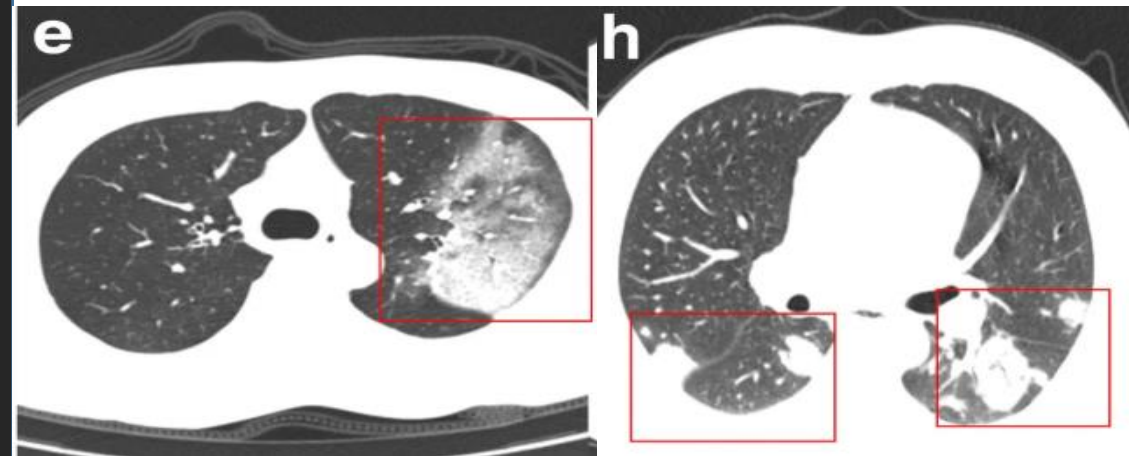


Baseline
anteroposterior
chest radiograph
shows patchy
ground-glass
opacities in right
upper and lower
lung zones and
patchy
consolidation in
left middle to
lower lung
zones.

- CT scan is an important screening tool for detecting Covid-19 due to its convenience and high sensitivity.
- The studies from China and Korea helped us to understand that the lobes of the lungs were severely affected in Covid-19 patients. In some cases left upper lobe, lower lobes or else all the lobes of the lungs were affected.
- CT scan helped us to identify the number of lesions and location of the lesion present in Covid-19 positive patients. The study of Korea helped us to identify 9 patients with 77 lung parenchymal lesions.
- Ground glass opacity or GGO is considered as an important Chest CT finding in Covid-19 positive patients which indicates filling of air spaces in the lungs by fluids. In a study of China, mixed GGO was seen in 50% cases and pure GGO lesions in 35% cases.
- Chest CT scan helped us to identify that the most vulnerable/affected region for a Covid-19 positive patient is the lower region of the lungs- majority of the opacities were visible in this region.
- CT scan is given more preference for higher sensitivity than X-ray, early detection of disease but poses challenges related to infection control- airflow, decontamination measures and ventilation.

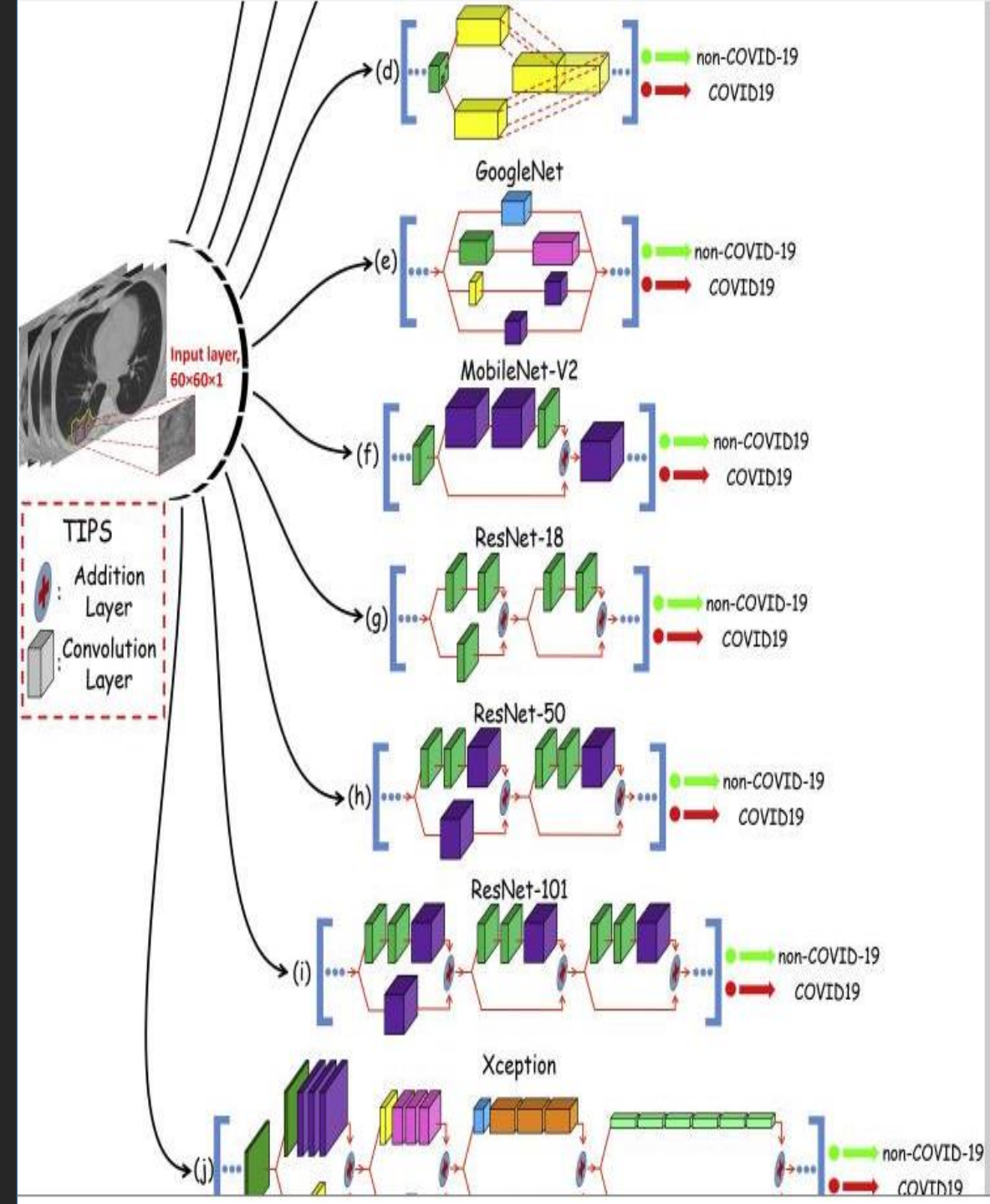


. The red arrows indicate GGO



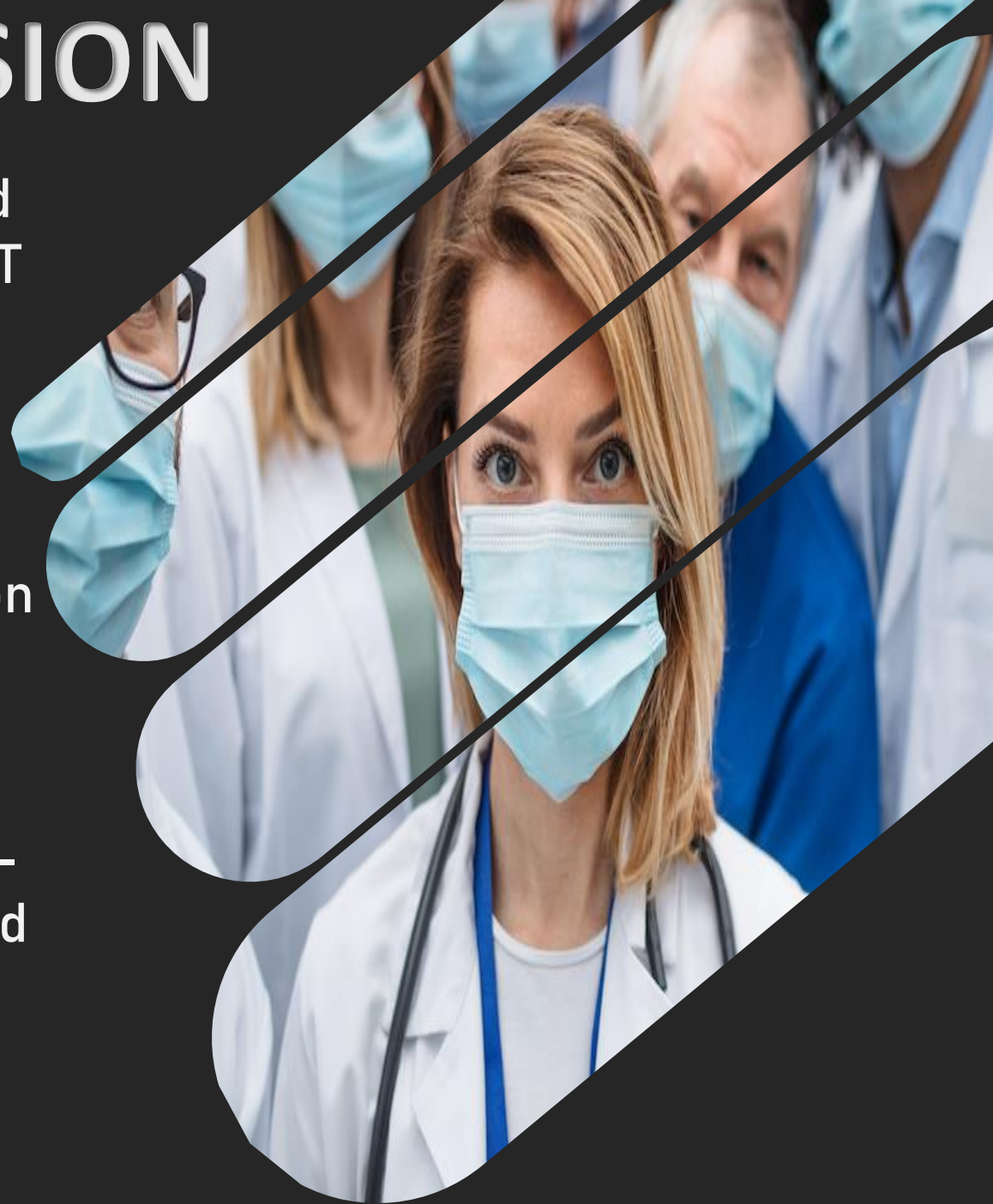
- E indicates patchy consolidation
- H indicates irregular solid nodules

- When deep learning models are applied with X-ray and CT images it enables the radiologist to give more accurate results. A radiologist requires time to read an X-ray or CT image.
- Therefore, by developing a deep learning model which identifies Covid-19 positive cases with more precision and it saves a lot of time during the pandemic when people are sick around the world.
- ResNet50 with SVM model gave the best results for X-rays in terms of accuracy, specificity, F1 score and lowest false positive rate in of Covid-19 detection.
- The deep learning models were able to differentiate between Covid-19 and other pneumonia cases with high accuracy. ResNet-101 proved to be the best CNN model for detecting Covid-19 from CT images when compared with other models due to its highest sensitivity and accuracy.



CONCLUSION

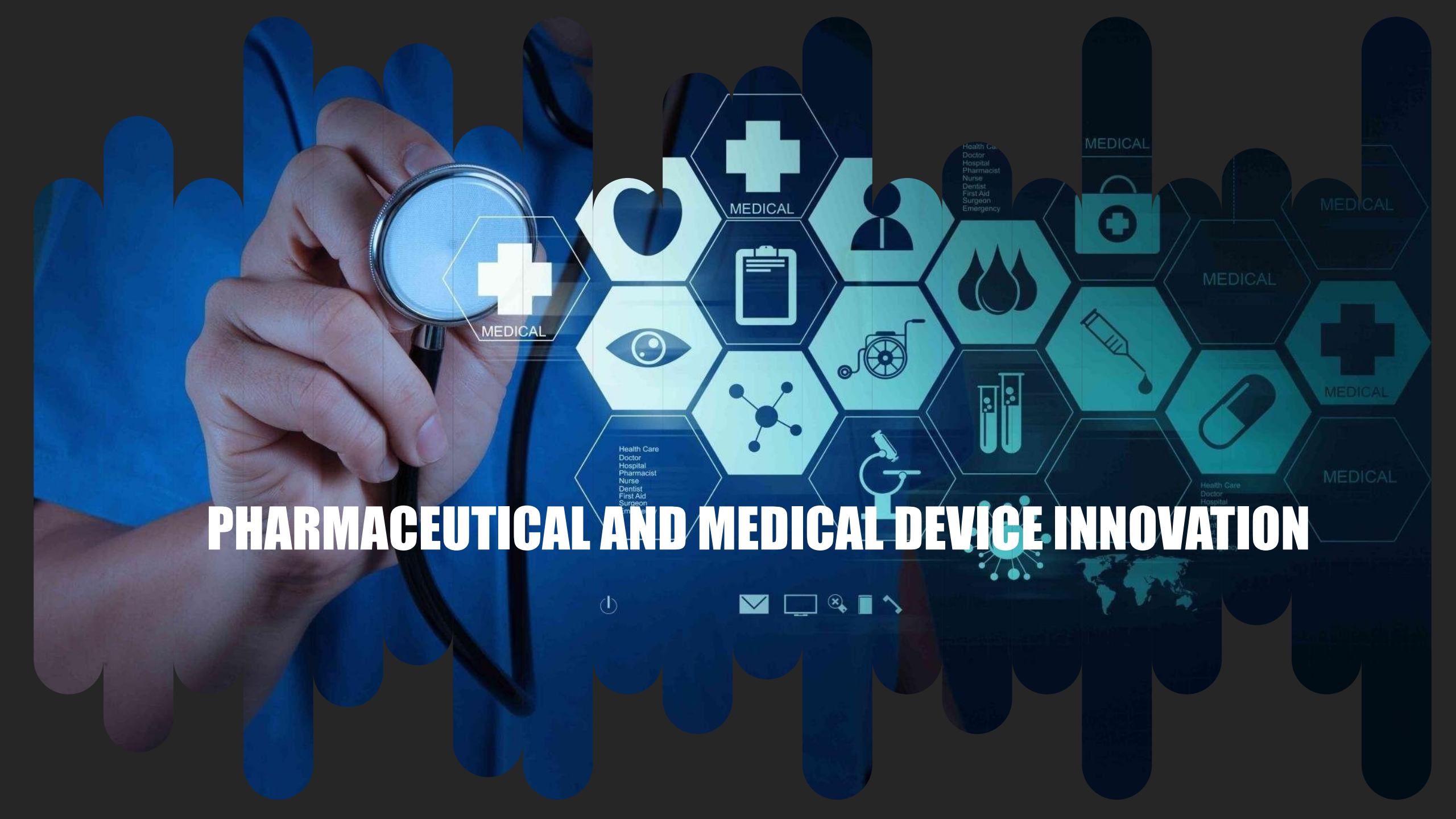
Fast and accurate detection of Covid-19 is need of the hour right now. Chest X-ray and chest CT are crucial in diagnosing Covid-19 patients and to keep a check on the health of the lungs. An imaging pattern of opacity with pure/mixed GGO, consolidation and lesions majorly affecting the lower region and peripheral region of the lungs. With the progression of the disease many patients were diagnosed with multiple affected lobes of the lung. The two deep learning models- ResNet-50 and ResNet-101 have helped in deriving accurate results and saves a lot of time. Therefore, X-ray and CT scans when combined with deep learning models can prove to be an effective diagnostic tool in covid-19.



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The image features a hand holding a stethoscope against a blue background. Overlaid on the background is a grid of hexagonal icons representing various medical and pharmaceutical concepts. The icons include a cross, a clipboard, a person, a heart, a wheel, a microscope, a virus, a pill, a syringe, a test tube, a network, an eye, a flame, a first aid kit, and a world map. The word 'MEDICAL' is repeated in several hexagons. At the bottom, there is a row of small icons: a power button, an envelope, a monitor, a magnifying glass, a trash can, and a wrench.

PHARMACEUTICAL AND MEDICAL DEVICE INNOVATION

INTRODUCTION

This course gives an in-depth view of two domains which are one of the most crucial parts of the healthcare industry-

- Pharmaceutical Industry
- Medical Device Industry

The course provides complete knowledge about the drug/device development process, challenges faced during development.

It covers the concept behind patent protection, components of branded drug cost, difference between prescription & OTC drugs as well as different classes of medical devices.

In addition, the course will discuss the different kinds of reimbursement coding- CPT, ICD-10, HCPCS-II. How codes are used and how payment is made to healthcare providers



METHODOLOGY

- The course is available on Coursera platform.
- The lectures were delivered via videos with the help PowerPoint presentations as resource.
- After the completion of each week a test had to be attempted with more than 80% score.
- When the course ended, a final assignment had to be submitted which signified the completion of the course.



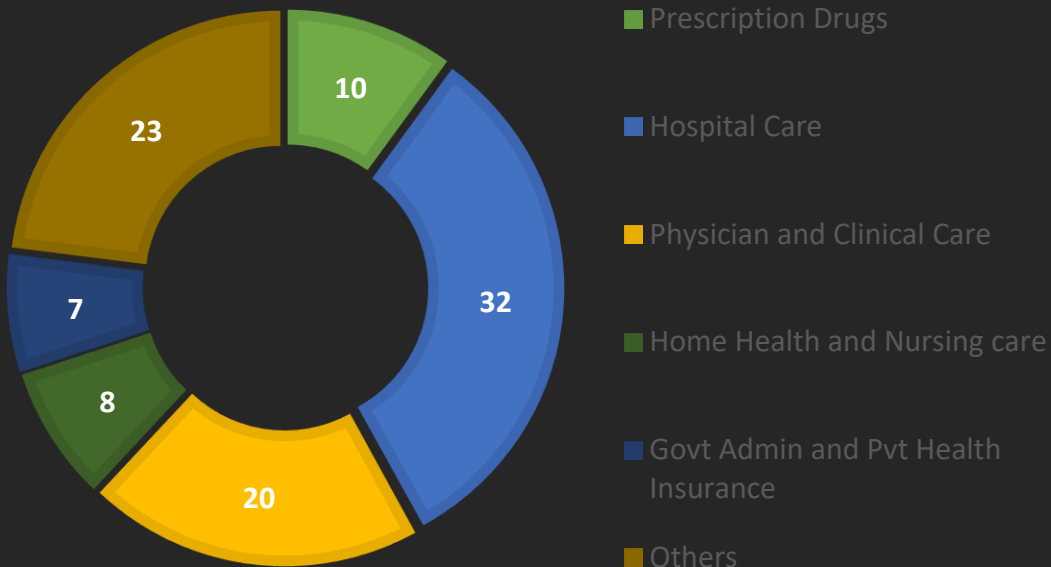
PERSONALIZED MEDICINE

Personalized medicine is the tailoring of medical treatment to the individual characteristics of each patient



HEALTHCARE DOLLAR

- ❑ Basically pharmaceuticals are half of what physician clinical services might be
- ❑ The personalized medicine components in cancer treatments can really be transformative to help really reduce long-term hospital calls, physician costs for the benefit that comes from prescription drugs.

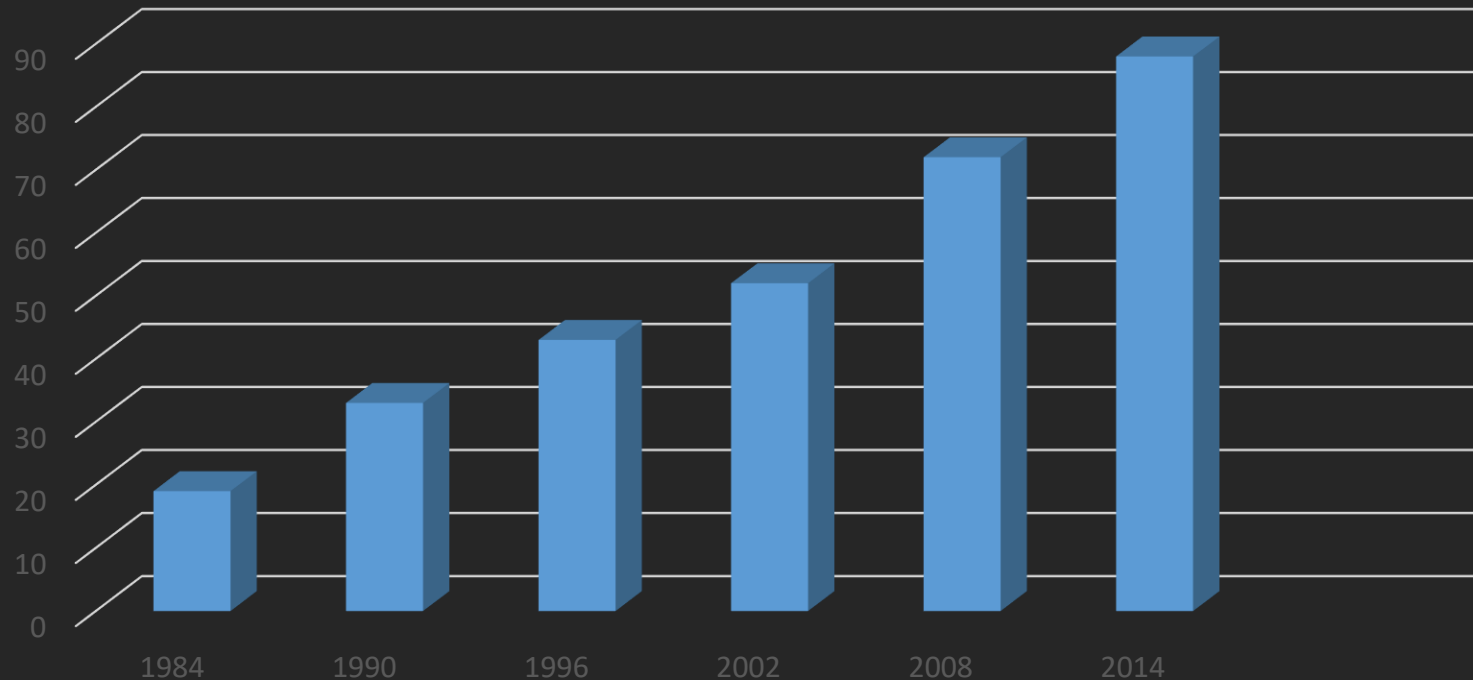


GENERIC AND BRAND NAME DRUG

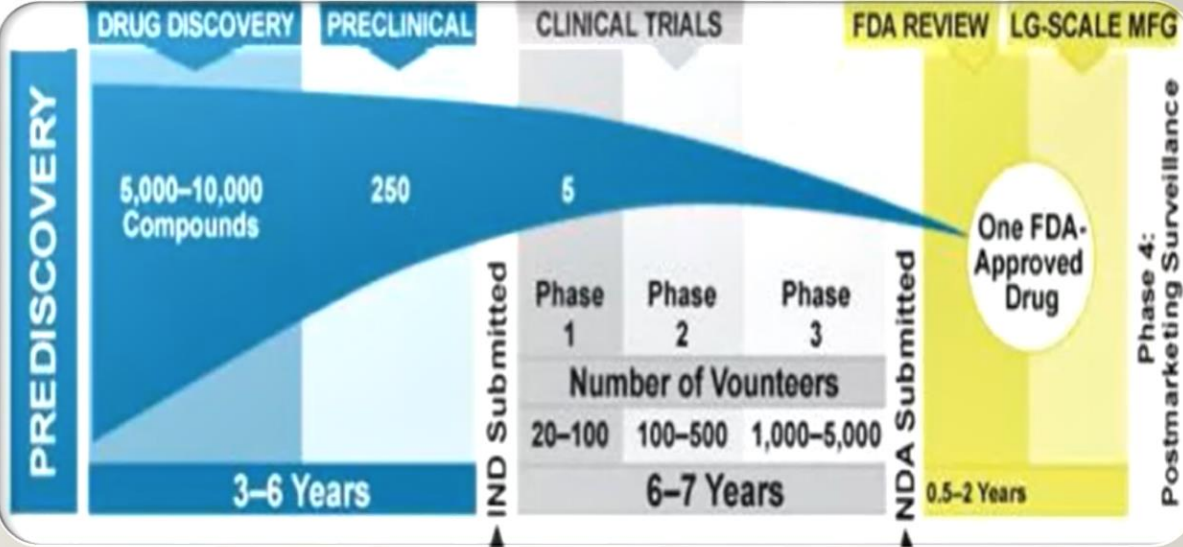
A generic drug is a [pharmaceutical drug](#) that contains the same chemical substance as a drug that was originally protected by [chemical patents](#)

A brand-name drug product is originally discovered and developed by a pharmaceutical company.

RISE IN SHARE OF GENERICS

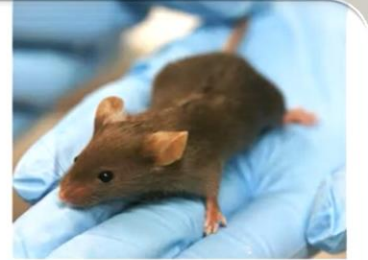


DRUG DEVELOPMENT PROCESS

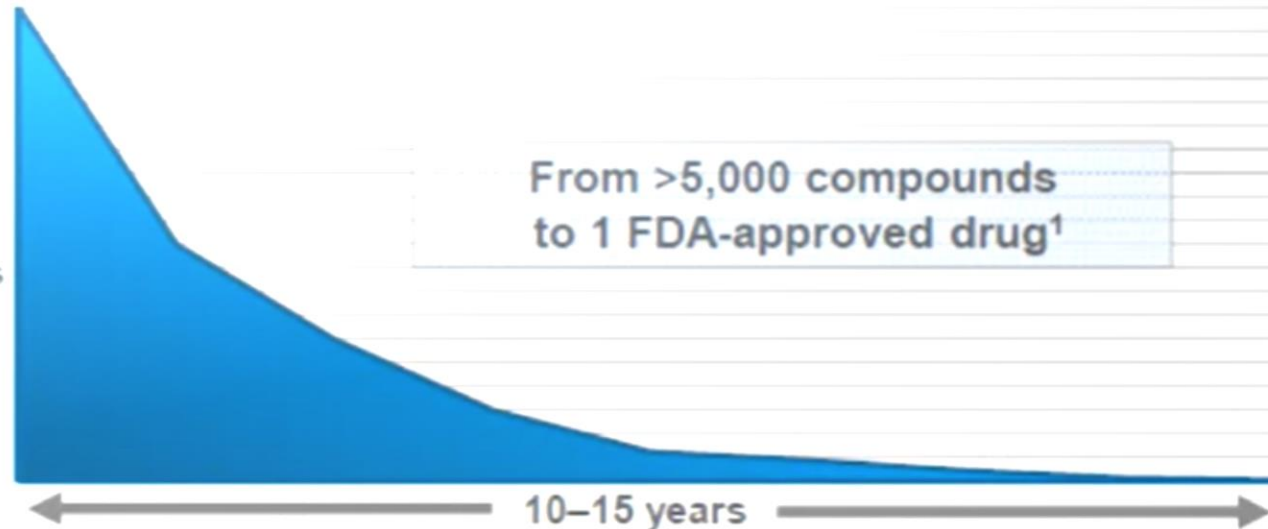


Getting a drug to market

- Disease target - possible drug candidates
 - Pre-clinical testing; R&D (1-3 yrs)
- Toxicology, "ADME"
- Clinical R&D (2-10 yrs; Av. 5yrs)
 - Phase 1 – healthy volunteers
 - Phase 2 – small patient group
 - Phase 3 – larger patient group
- Regulatory approval (2-10(!) yrs)
- Market
- Phase 4 – long term monitoring

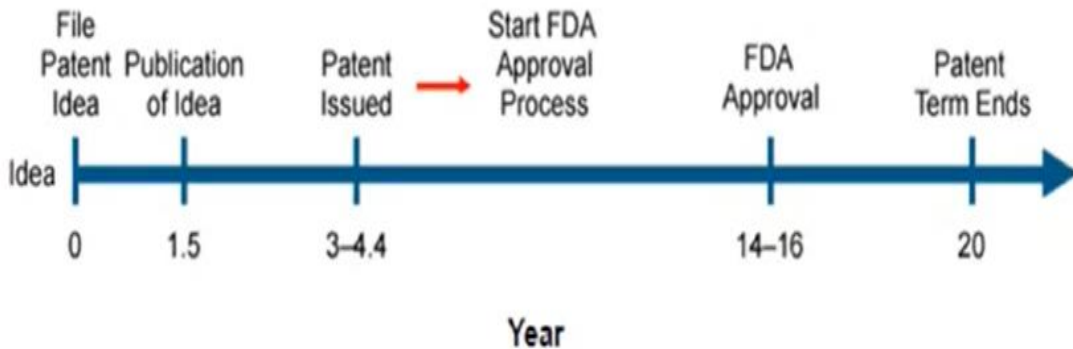


Number of compounds



CHALLENGES IN DRUG DEVELOPMENT

Example of Years From Conception to Product Idea



- Prescription drug prices decrease significantly over time
- Cost of a generic medicine is typically up to 80 percent less than that of the brand medicine.

Source: IMS May, 2015

MEDICINE		BRAND NAME THEN	vs.	GENERIC NOW	% CHANGE
DIOVAN HCT [®] <i>Hypertension</i>	2010	\$87		\$13	-85%
LIPITOR [®] <i>Cholesterol</i>	2010	\$85		\$4	-95%
PLAVIX [®] <i>Blood Thinner</i>	2011	\$166		\$5	-97%
SEROQUEL [®] <i>Schizophrenia</i>	2010	\$87		\$3	-97%
ZYPREXA [®] <i>Schizophrenia & Bipolar Disorder</i>	2010	\$393		\$8	-98%

Figures represent the average annual price for 30 pills of the most commonly dispensed form and strength. "Then" price represents the average price in the year prior to generic entry. "Now" price represents the average price in CY 2014.

FOOD AND DRUG ADMINISTRATION

- ❑ The FDA is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices
- ❑ FDA's primary objective in reviewing an investigational new drug (IND) are in all phases of the investigation, to assure the safety and rights of subjects
- ❑ Once the FDA approves the drug for a specific indication or indications, the drug then gets an NDC (National Drug Code) number.



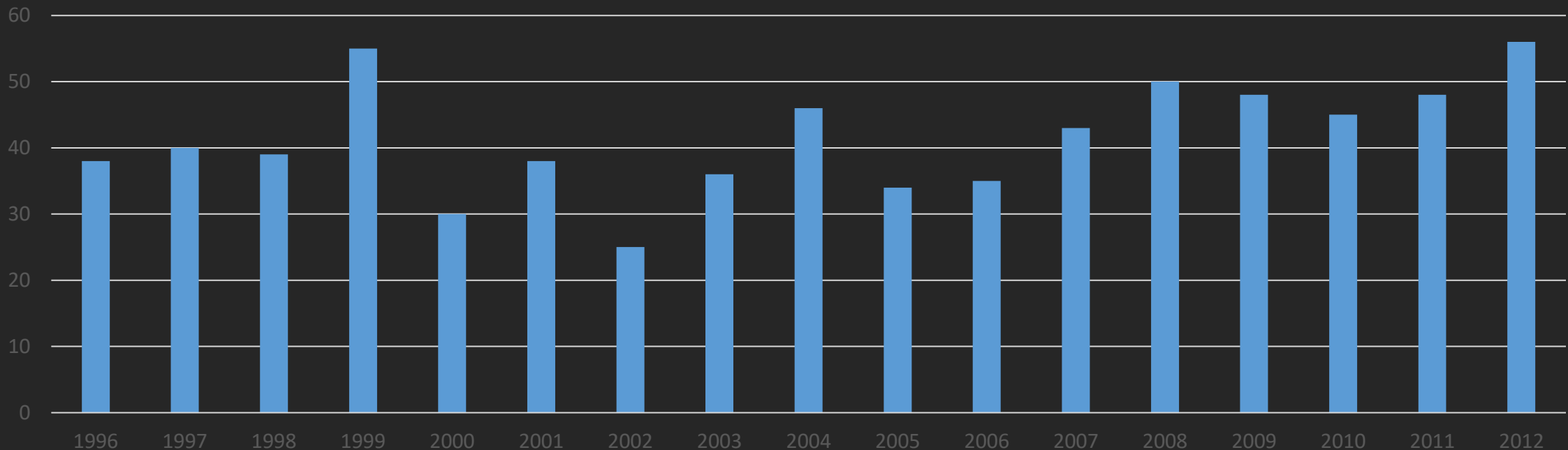
INVESTIGATIONAL NEW DRUG

FDA team approach to IND review:

- Regulatory Project Manager
- Chemistry, manufacturing and controls (CMC) reviewer
- Pharmacology/toxicology reviewer
- Clinical reviewer
- Statistical viewer



Yearly IND Submission



PRIVATE INSURANCE

Group Insurance

Individual Insurance

Fully Insured

Self Insured



MEDICARE

Medicare is the federal government program that provides healthcare coverage (health insurance)

Different parts to Medicare-

- ☐ Medicare part A
- ☐ Medicare part B
- ☐ Medicare part C
- ☐ Medicare part D



MEDICARE CLAIMS

- ✓ Most claims are processed electronically
- ✓ CMS (Center for Medicare and Medicaid Services) contracts out with different organizations to do the claims processing
- ✓ Carriers- handle claims of physicians
- ✓ Financial Intermediaries- handles claims of hospitals, skilled nursing facilities, home health agencies, renal dialysis facilities and hospices.
- ✓ The carriers and FI determine if a bill should be paid.



MEDICARE COVERAGE DECISIONS

- ✓ Medicare decides what to cover
- ✓ Usually specify that a procedure is covered if certain conditions are present



BIO-SIMILARS

A biosimilar is a biologic medical product (also known as biologic) highly similar to another already approved biological medicine.



Prescription drugs are-

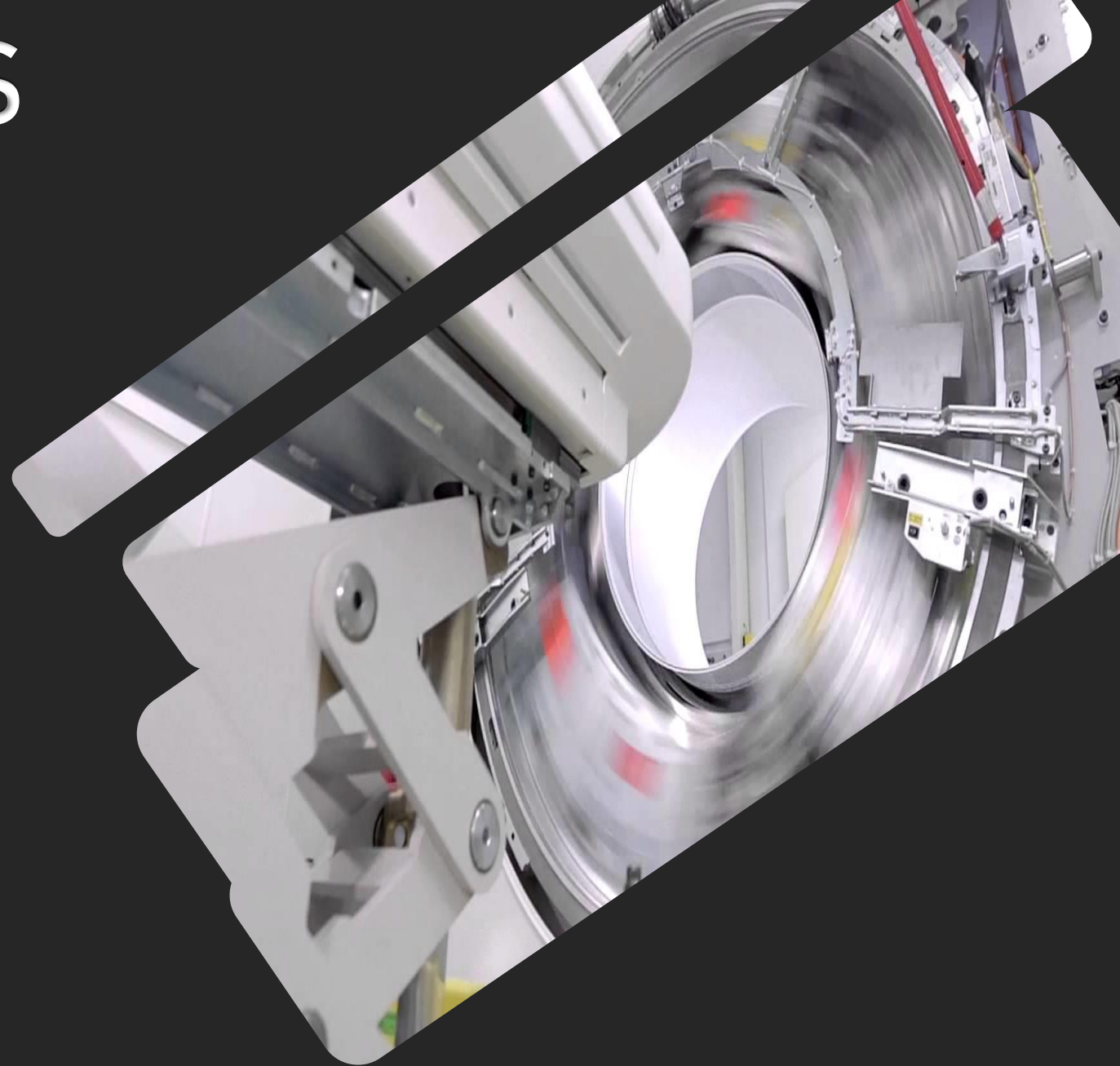
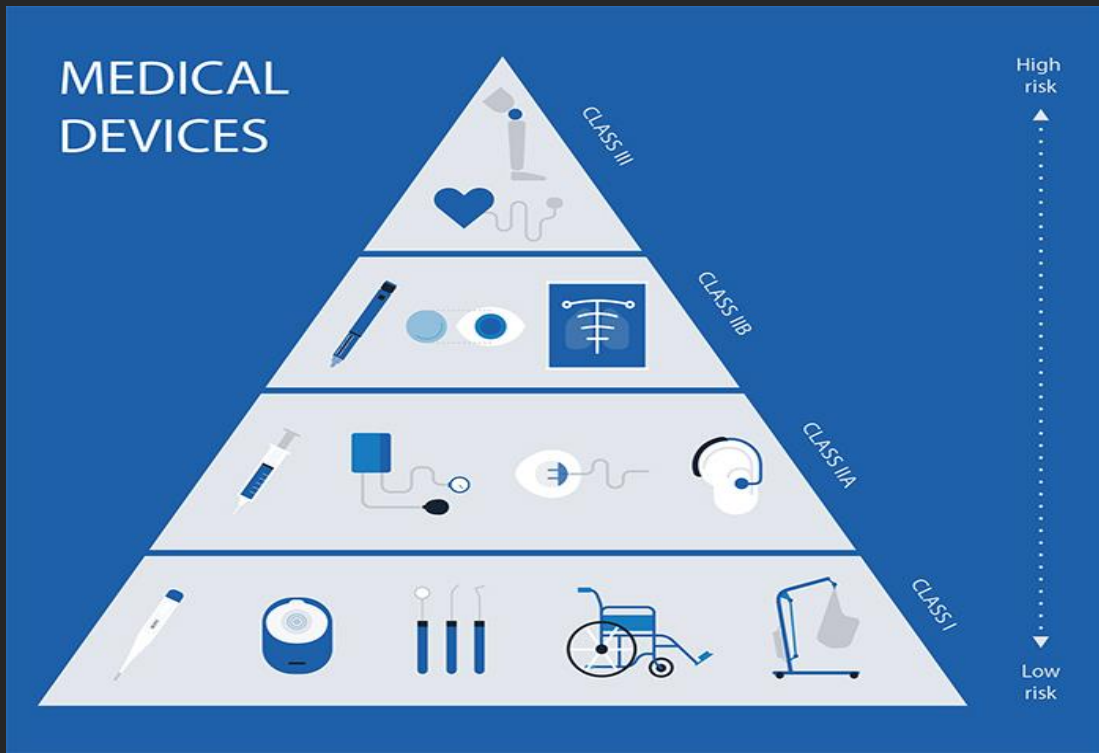
- ☐ Prescribed by the doctor
- ☐ Bought at pharmacy
- ☐ Prescribed for and intended to be used by one person
- ☐ Regulated by FDA through the New Drug Application (NDA) process.

OTC drugs are-

- ☐ Drugs that do NOT require a doctor's prescription
- ☐ Bought off-the-shelf in stores
- ☐ Regulated by FDA through OTC Drug monographs. OTC drug monographs are a kind of "recipe book" covering acceptable ingredients, doses, formulations, and labeling.

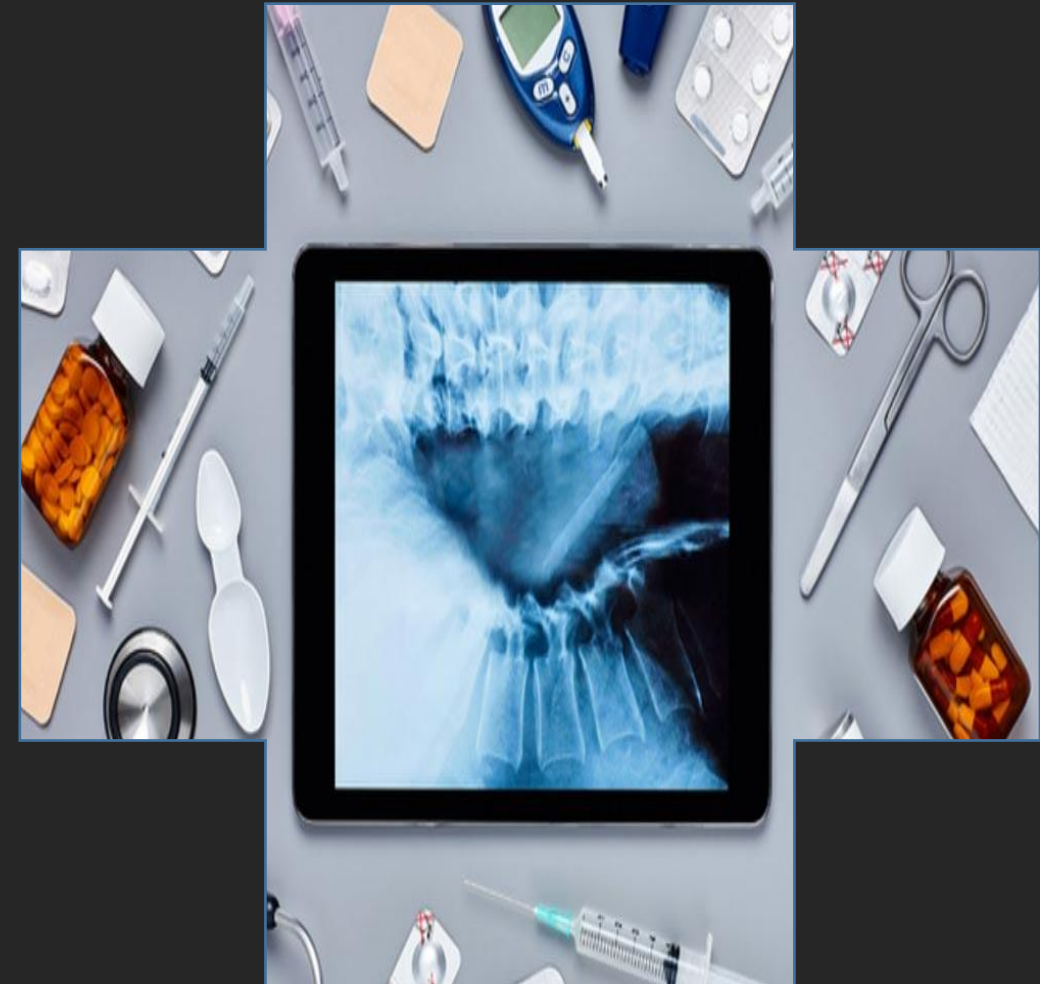
MEDICAL DEVICES

A medical device is any device intended to be used for medical purposes. Medical devices benefit patients by helping health care providers diagnose and treat patients and helping patients overcome sickness or disease, improving their quality of life



GOVERNMENT REGULATIONS AND MEDICAL DEVICES

- ❑ The government agencies determine approval and payments
- ❑ The role of government is the most important difference between marketing non-medical technologies and medical technologies
- ❑ Need to understand the process and the bureaucratic details in order to plan the technology assessment.



HOW A NEW TECHNOLOGY MAKES IT TO THE MARKET

Four important steps-

- ✓ Obtain a patent
-It takes 6 months to 2 years for the patent office to grant a patent. Patent life is 20 years from application date.
- ✓ Regulatory approval from the FDA that the new device or drug may be marketed.
- ✓ Payers must agree to cover the drug/device/procedure.
- ✓ Providers must be persuaded to use/proscribe the innovation.



REIMBURSEMENT CODING

CPT

CURRENT PROCEDURAL TERMINOLOGY

ICD-10

INTERNATIONAL CLASSIFICATION OF DISEASE

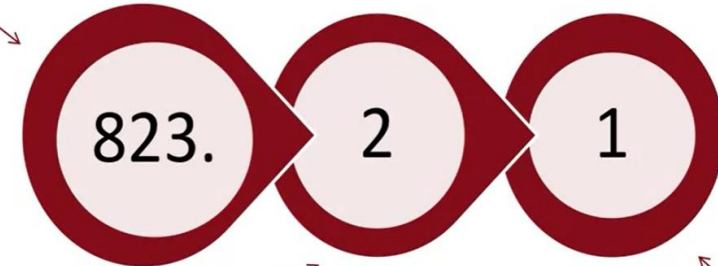
HCPCS-II

HEALTHCARE COMMON PROCEDURAL CODING
SYSTEM- II

Diagnosis Codes

Used on all claims (up to 5 digits)

Specifies diagnosis: "Fracture of tibia and fibula"



Specifies subtype of diagnosis: "Shaft closed"

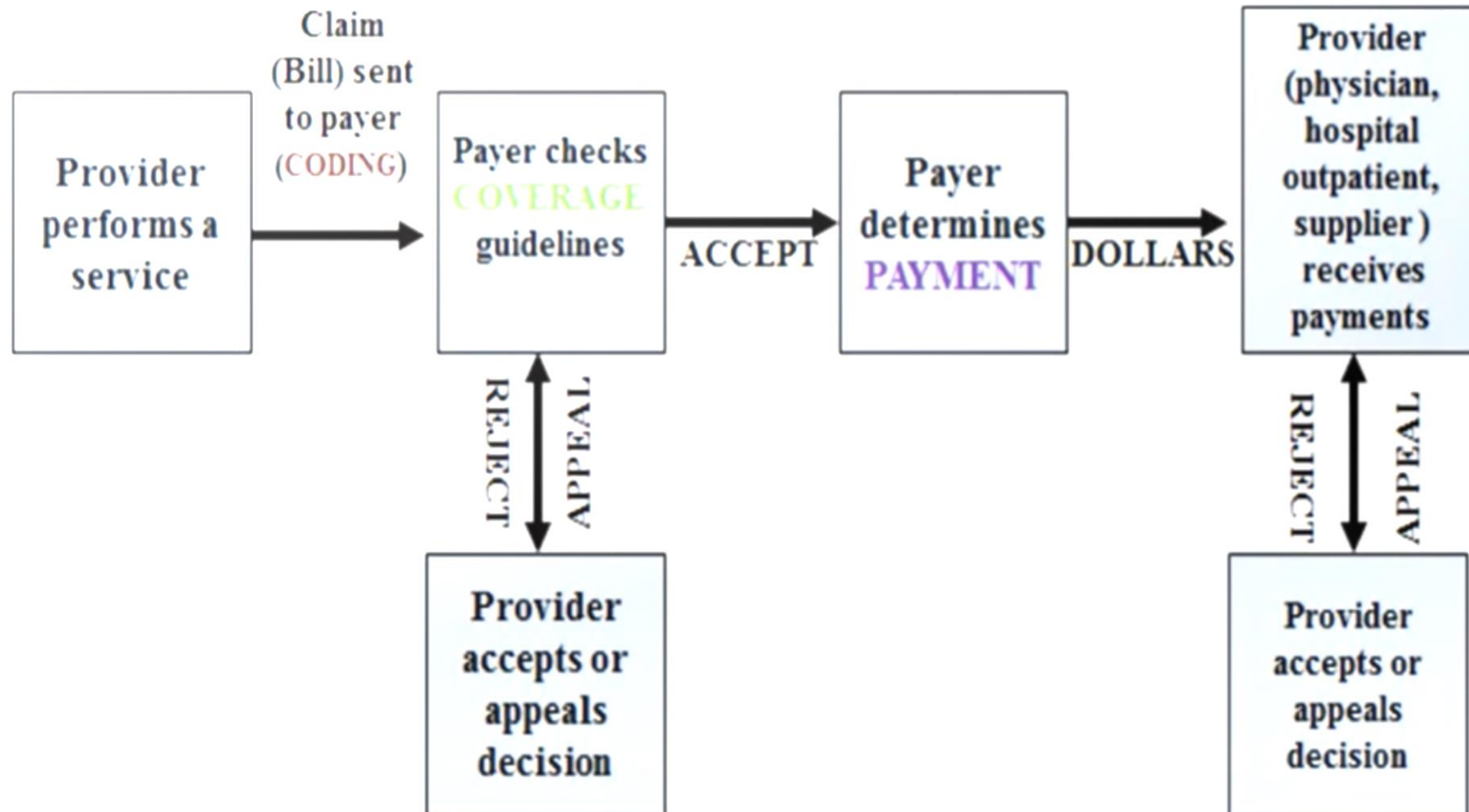
Gives additional detail: "fibula alone"

6

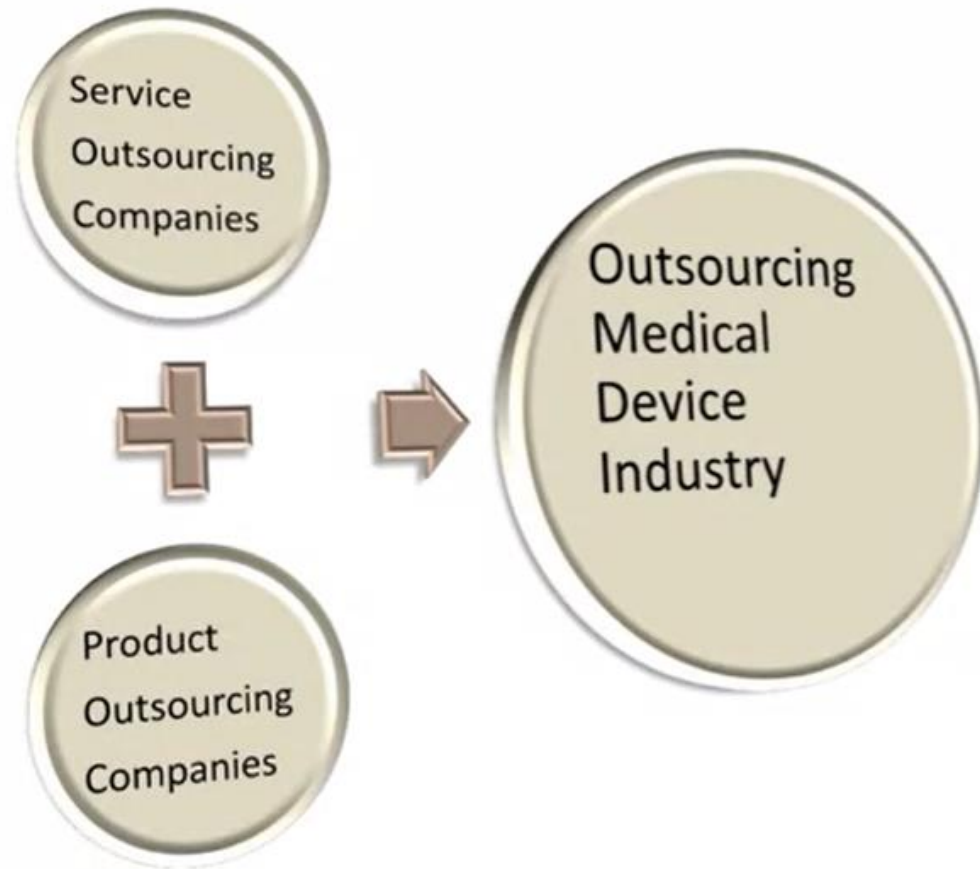
HOW CODES ARE USED?

- ☐ Used on insurance claims forms to link services/supplies/devices/drugs to payment
- ☐ Establish medical necessity
- ☐ Define coverage and payment rates
- ☐ Analyze healthcare utilization which can affect future payment rates and Medicare audit reviews.
- ☐ Tracks diseases (epidemiological research)

REIMBURSEMENT TRAID IN ACTION



OUTSOURCING MEDICAL DEVICE INDUSTRY



Service Outsourcing

- ☐ New and enhanced outsourcing concept
- ☐ Early growth phase
- ☐ High growth market
- ☐ Focus areas-
 - Reduced cost
 - Innovation
 - Faster production
 - Reduced rollout time
 - Solution for regulatory issues

Product Outsourcing

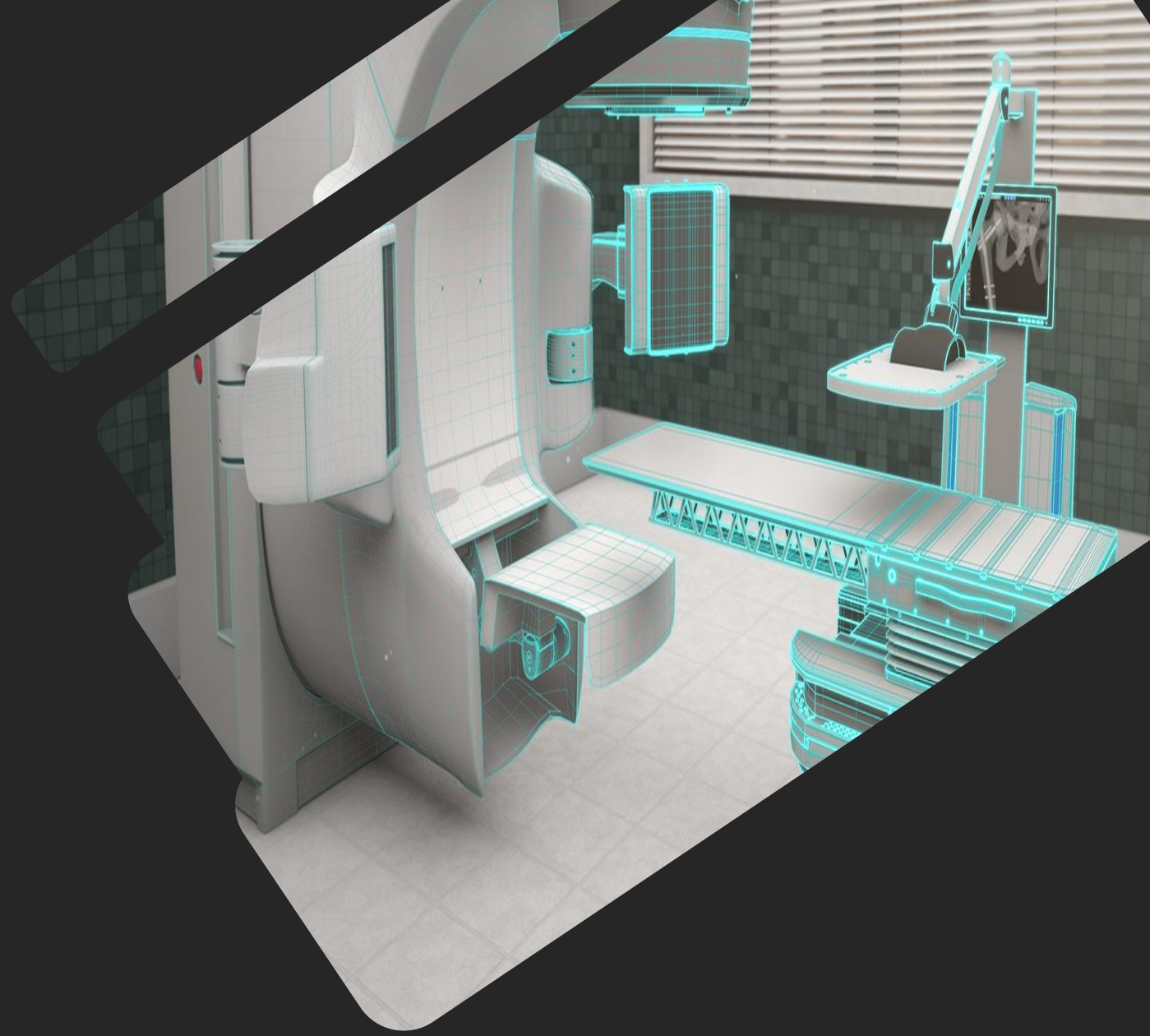
- ☐ Older outsourcing concept
- ☐ Relatively matured market
- ☐ Late growth phase
- ☐ Focus areas-
 - Contract manufacturing
 - Re-sellers module

510(k)

A 510(K) is a premarket submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent, to a legally marketed device

510(k)-FRIEND OR FOE?

- ✓ Quick to market
- ✓ Easy to define market space on precedent
- x Application may not apply and you wasted valuable time
- x FDA standard for approval evolving towards PMA required and expensive clinical trials



Thank
you!!!

