Al Mustaqbal University
College of Medicine

Computer Science

Lecture 7
Machine Learning in Medical Devices

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Machine Learning in Medical Devices

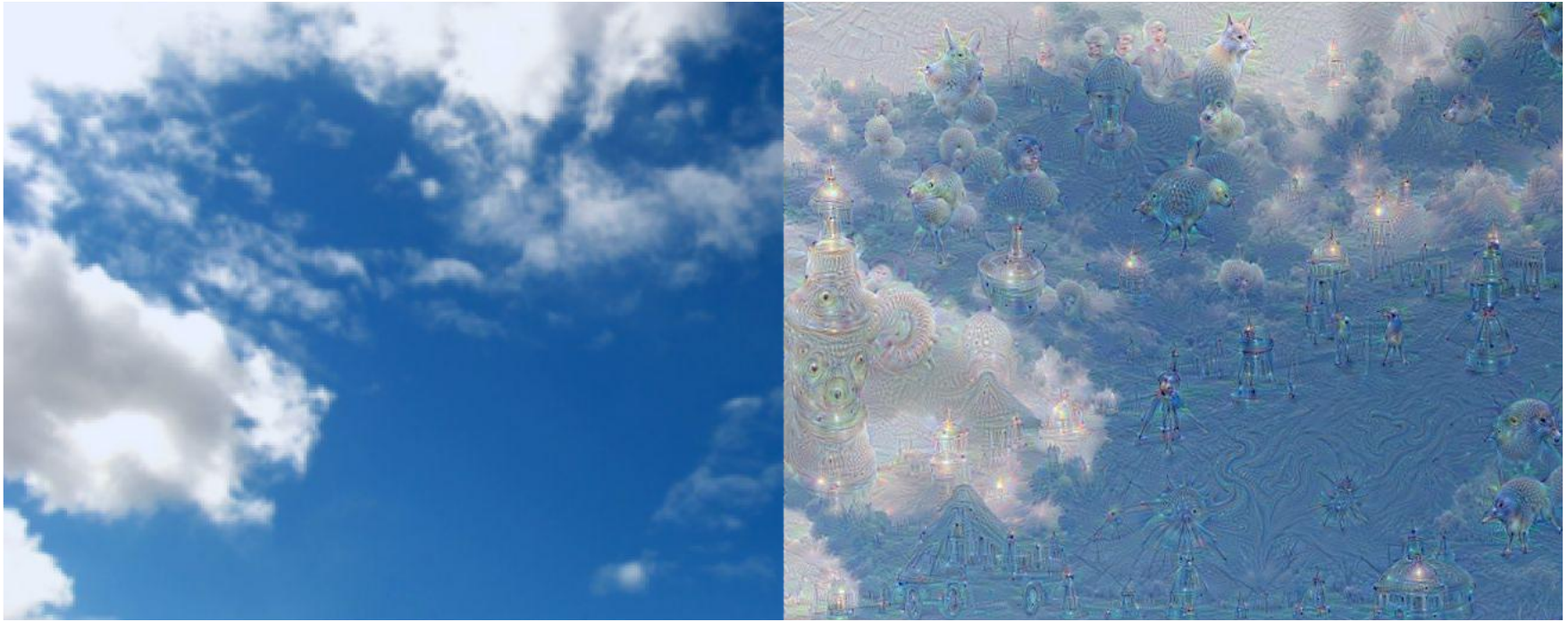
- Agenda
  - Machine Learning
    - What is it?
    - Why is this special?
    - The FDA's treatment
  - Use case: Medical devices
    - How to make use of AI or ML in a medical device
  - Medical Device Safety Considerations
  - Development lifecycle with Machine Learning
  - Safeguards for Medical Devices with Machine Learning

Google’s DeepDream

What does a network trained to see dogs see in an image without dogs?

Initially it was invented to help scientists and engineers to see what a deep neural network is seeing when it is looking in a given image.

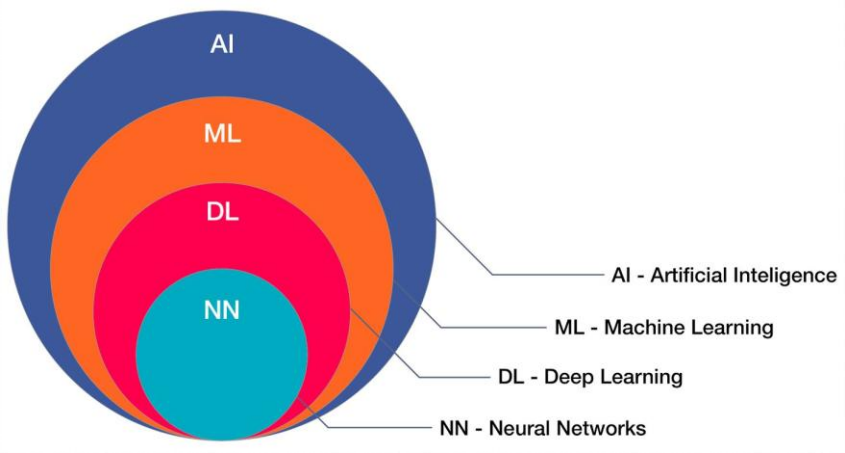
Inceptionism

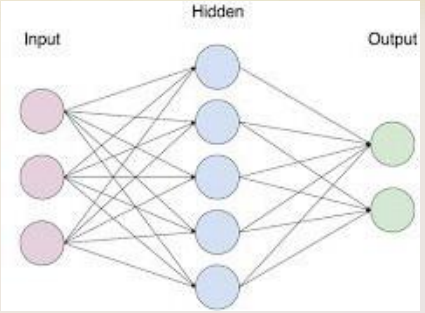


What is AI/ML?

Without using explicit instructions

Relying on patterns and inference instead

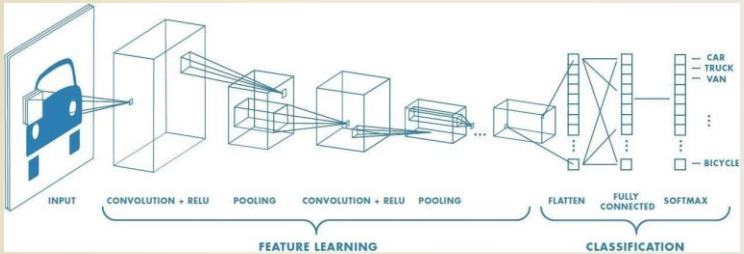




Food and Drug Administration (FDA) defines ML as

"…techniques used to design and train software algorithms to learn from and act on data…"

"…when intended to treat, diagnose, cure, mitigate, or prevent disease or other conditions, are medical devices…" [1]



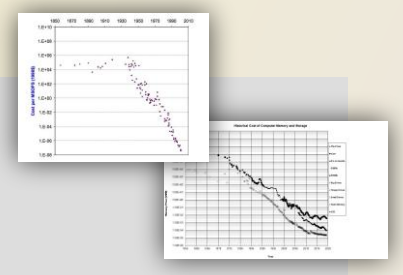
Why ML is different. What's hard?

Different from conventional algorithms

Wikipedia

"without using explicit instructions, relying on patterns and inference instead."

Why ML now?



Compute power
Since 1984,

Processor power
Up ~1,000,000X

Data storage
Up ~5,000,000X

ML applications

Recognition, categorization but not procedural

Not …
- **word processors**
- **email clients**
- **multimedia players**
- **video games**

Challenges

Apocryphal, tanks or clouds?

Verification, local minima

Overtraining (remembering the answers)

Prove "Ground truth" (vs. gold standard)

The Problem

ML products with algorithms that continually adapt based on new data require a new pre-market submission (510K).

New from the FDA

FDA proposes regulatory framework for modifications to an AI/ML

https://www.fda.gov/media/122535/download

FDA's Proposed Framework

Summary,

FDA allows **trusted manufacturers** to make **pre-approved**

changes if they follow a **predetermined change control plan**

FDA's Proposed Framework

SaMD	Software as a Medical Device	(phone, laptop, tablet)
SPS	SaMD Pre-Specifications	(this is what's going to change)
ACP	Algorithmic Change Protocol	(how the change is controlled)
TPLC	Total Product Life Cycle	(an ML lifecycle that includes data)

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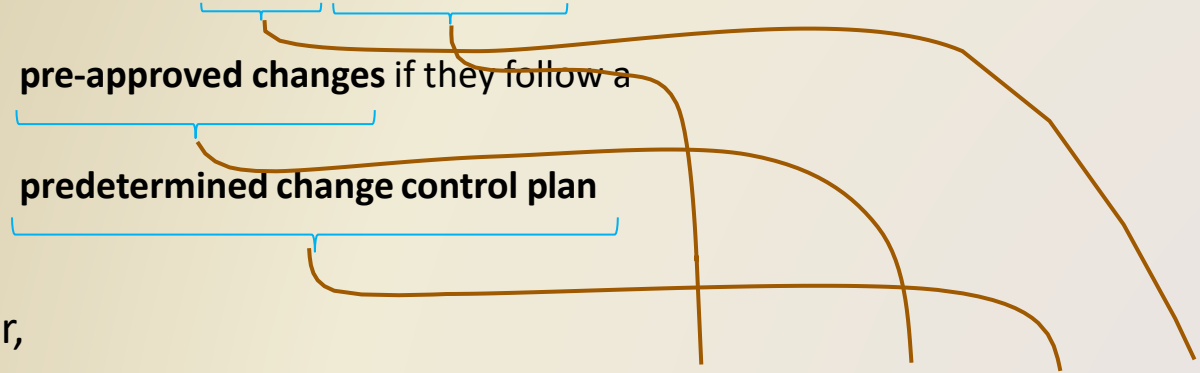


or,

FDA allows changes to an ML-enabled **SaMD** with an **SPS** using **ACP** in a **TPLC**.

SaMD

Software as a Medical Device

- Software that runs on a **generic computing platform** (computer, mobile phone, tablet computer)
- "**Software** intended to be used for one or more **medical** purposes that perform these purposes without being part of a hardware **medical device**.“(IMDRF)
- No specially made hardware, doesn’t control hardware motors, sensors, switches

SaMD Examples: Viewer for MRI images, ECG app, radiological image analysis (Computer Aided Detection)

SPS & ACP

SPS – SaMD Pre-Specification

- Anticipated modifications to performance or inputs or **intended use**
- A **region of potential changes**, around specifications and labeling

ACP – Algorithm Change Protocol

- Plan to control risks while making changes
- Step-by-step process
  - Data management
  - Re-training
  - Performance evaluation
  - Update procedures

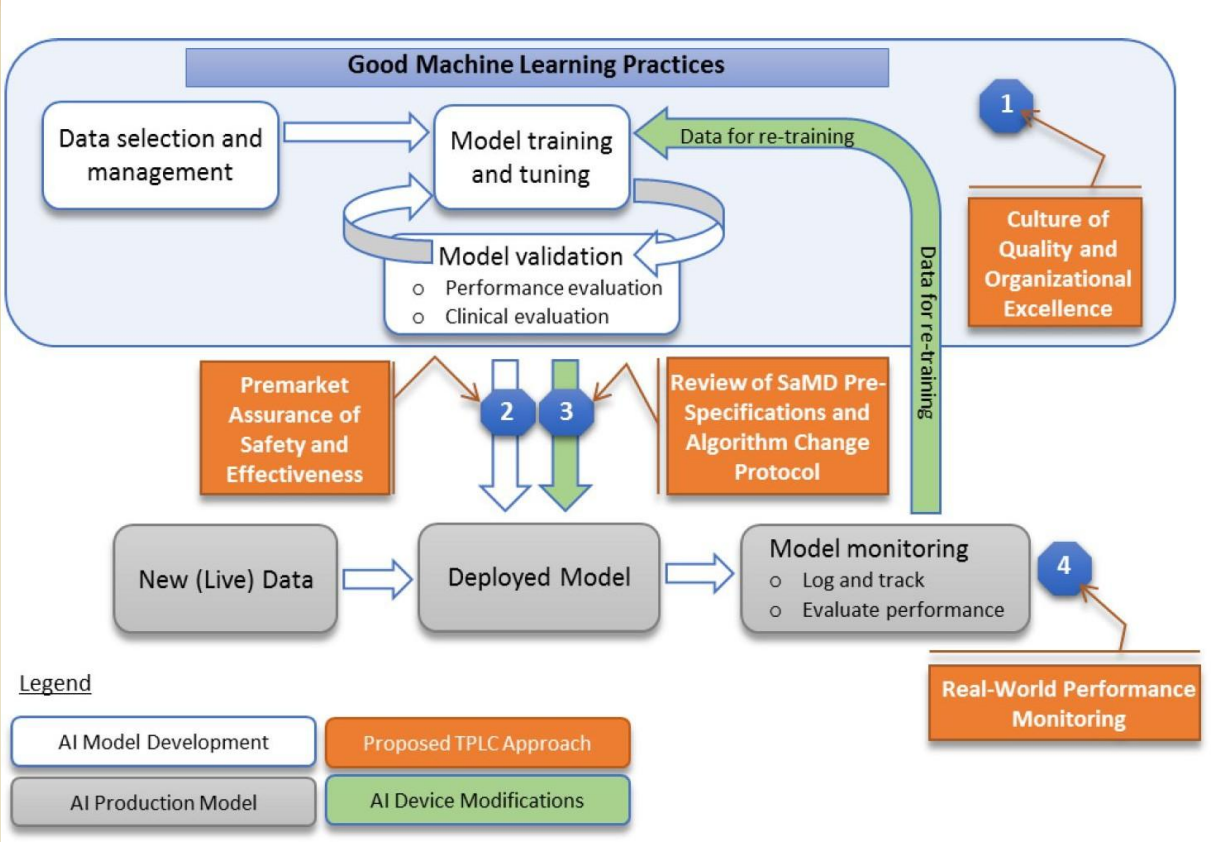
TPLC – Total Product Life Cycle

A regulatory framework

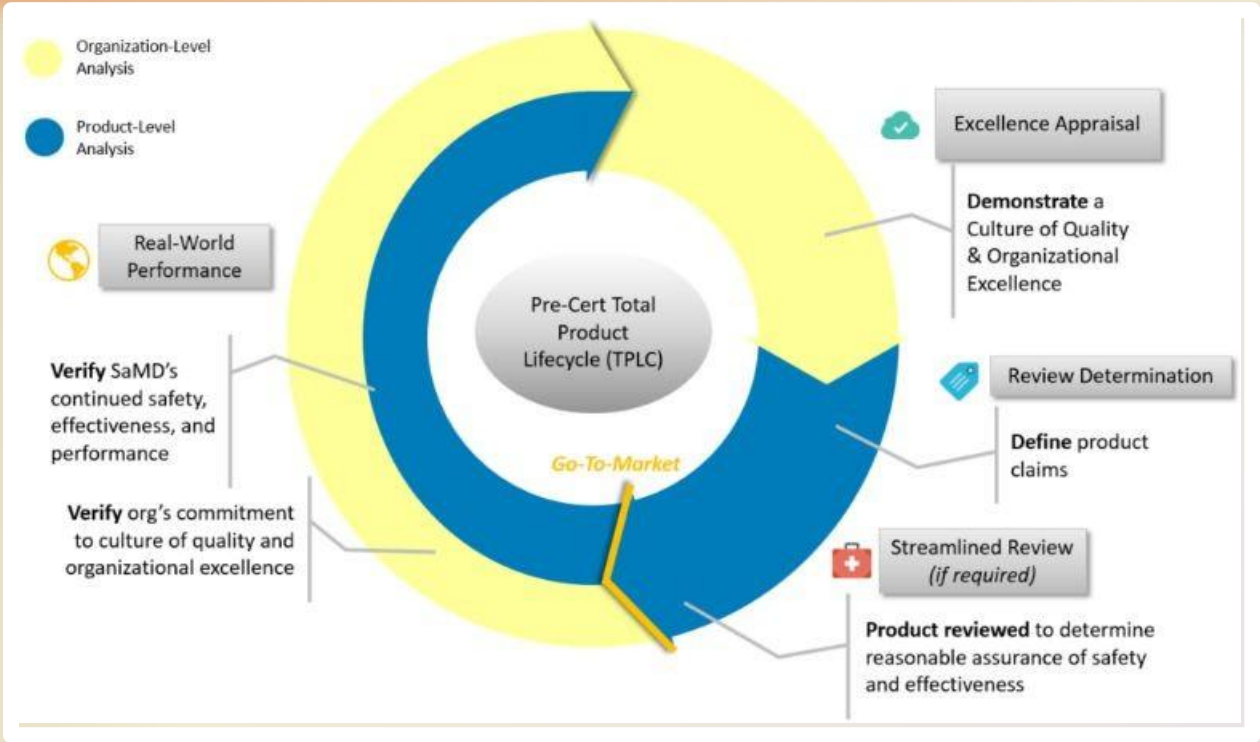
4 principles:

1. Quality systems and good machine learning practice **(corporate reputation)**
2. Initial premarket assurance of safety and effectiveness **(premarket review)**
3. Approach for modifications after initial review with an established SPS and ACP **(change plan)**
4. Transparency and real-time monitoring of AI/ML-based SaMD **(PAY ATTENTION)**

TPLC on an AI workflow

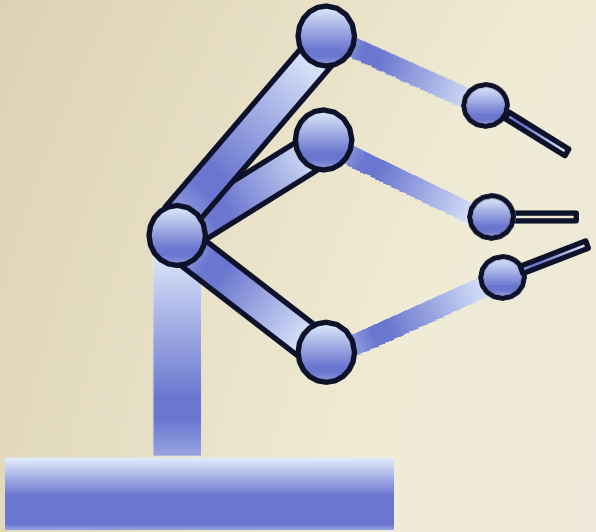


FDA's Software Precertification (Pre-Cert) Program



https://www.fda.gov/medical-devices/digital-health/digital-health-software-precertification-pre-cert-program

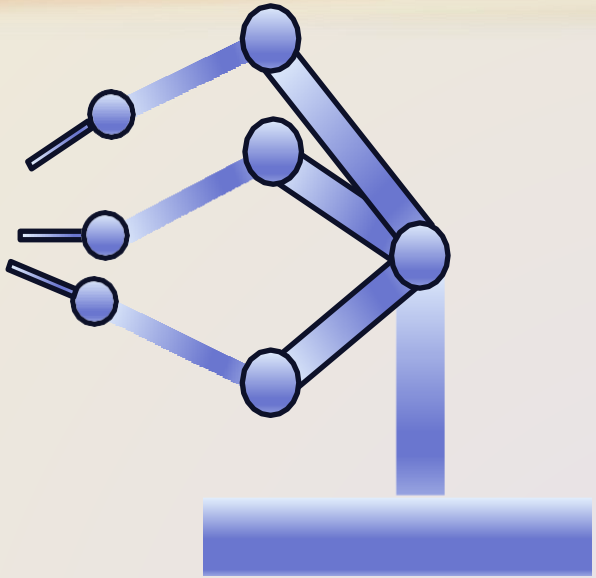
Software Foundation — Safe



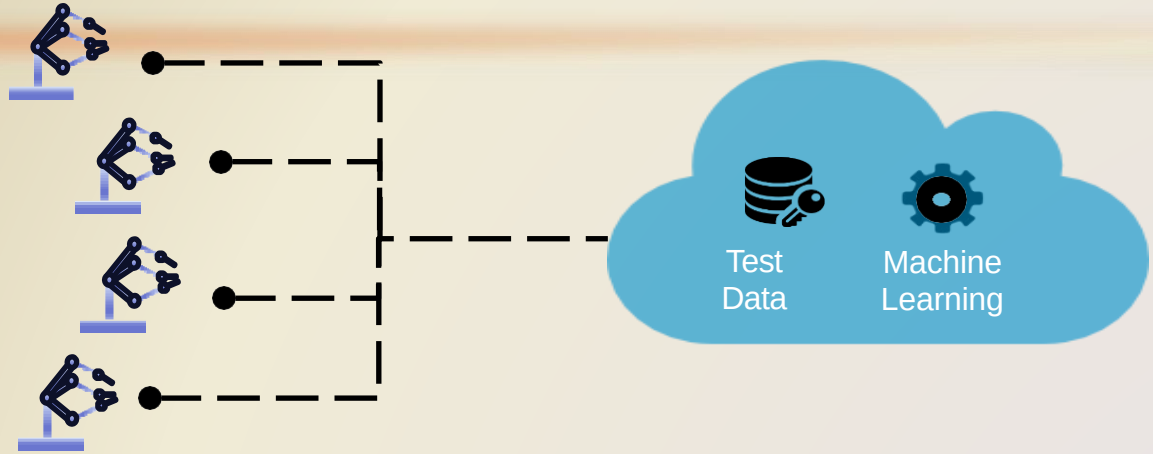
- Safe Real Time OS (QNX)
  - Certificate IEC 62304/61508
  - Safety Manual
  - Fault Tolerant
  - APIs (POSIX)
  - Networking
  - Well Tested/Deployed

Software Foundation — Security

- Security Features
  - User permissions
  - Application permissions
  - FIPS 140-2
  - OpenSSL
  - Secure File System
  - Lifecycle Management
  - Virus Detection/Eradication



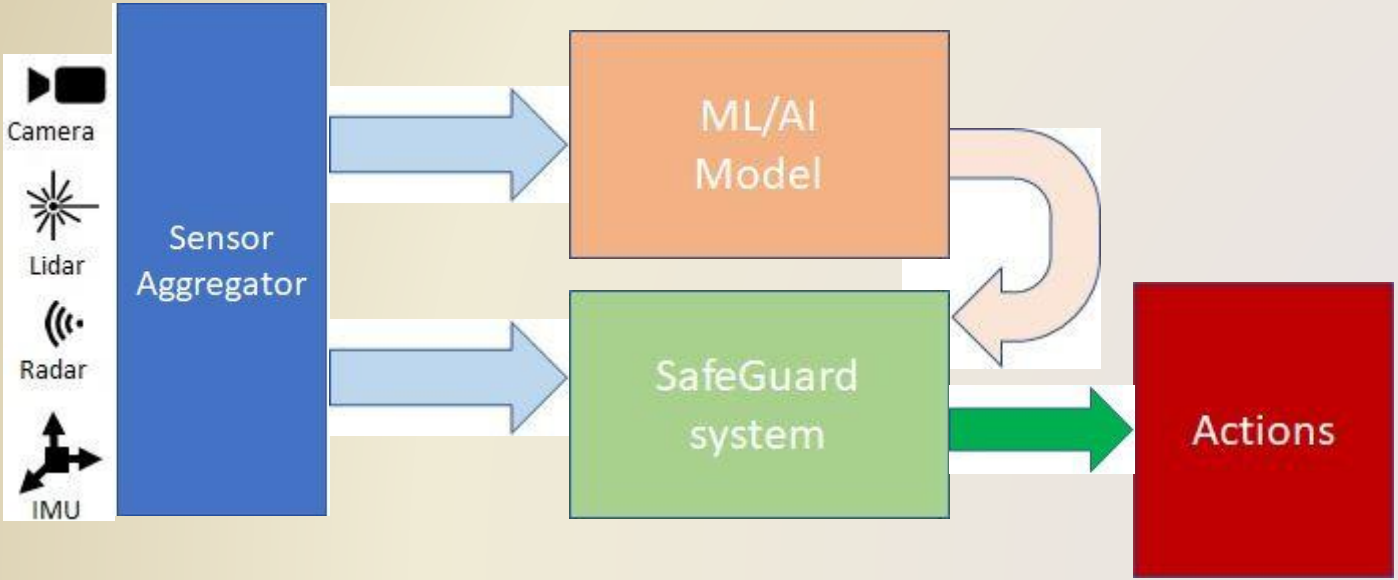
Machine Learning in Cloud



- Collect test set data on Edge
- Propagate data securely to cloud (On/Off Premises)
- Train the model
- Distribute model securely to Edge devices

SafeGuards

- Training wheels so you cannot fall.
- Validating the output of the model. Ensuring that it does not break major rules.



Summary

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