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UNLOCKING AI INNOVATIONS: NAVIGATING FDA'S GUIDANCE DOCUMENTS FOR AI/ML ENABLED DEVICES

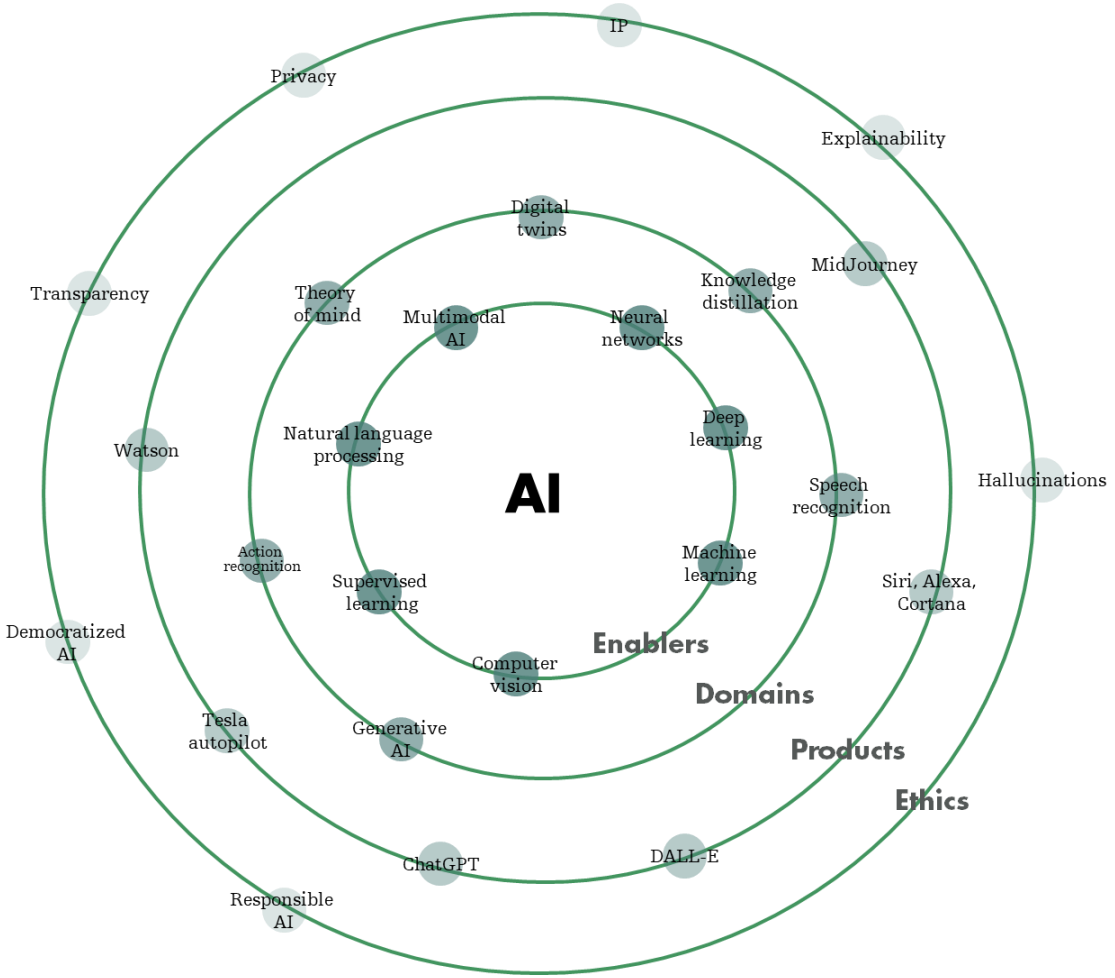
CONTRIBUTORS

Ganesh Saiprasad, PhD	VP of Innovation, Product Development, RA/QA	Focal One
Diane Johnson	Sr. Director of U.S. Regulatory and Global Digital Health Policy	J&J Medtech
Anupama Govindrajan, PhD	Director, Regulatory Affairs – Digital Health	J&J Medtech
Manan Hathi, MS, RAC (US)	Sr. Manager, Digital Health Regulatory Policy & Intelligence	Stryker

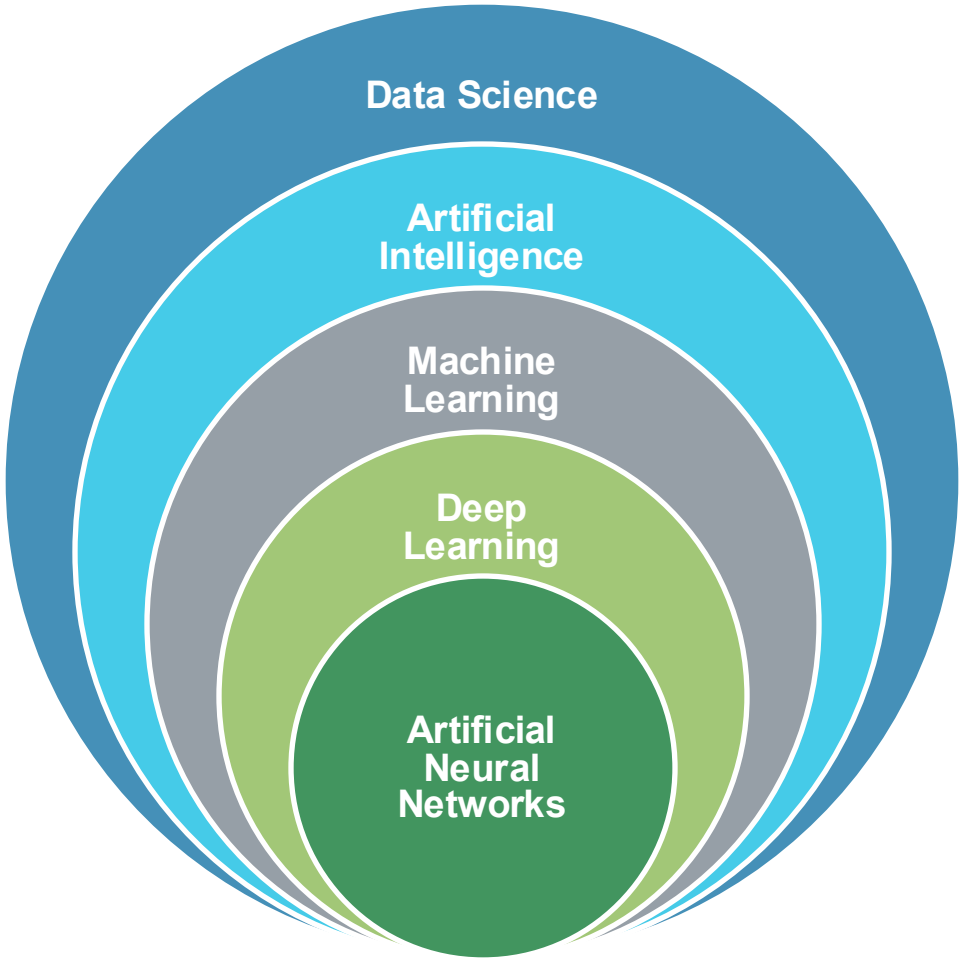
Introduction

AI is vast and changes rapidly

Today's key terminology and concepts



Introduction



- AI: Machines that simulate human intelligence
- ML: Providing machines the ability to learn from experience
- DL: Algorithms that learn to recognize patterns in data. Typically uses artificial neural networks

TERMS AND DEFINITIONS

Model	• Mathematical construct that generates an inference or prediction based on new input data
AI-DSF	• Device software function that implements one or more "AI models"
AI-enabled Device	• A medical device that incorporates one or more AI-DSF

GENERAL PRINCIPLES

Model Development and Description

Transparency / Trustworthiness

TPLC Approach

Postmarket Monitoring

Predetermined Change Control Plans

CONTENT RECOMMENDATIONS

- Device Description
- User Interface / Labeling
- Risk Assessment
- Data Management
- Model Description and Development
- Validation
- Performance Monitoring
- Cybersecurity
- Public Submission Summary

R&D CONSIDERATIONS

Data & Development

Ganesh Saiprasad, PhD

DATA MANAGEMENT

Why should it be included in the submission?

- Performance depends on quality, diversity and quantity
- Identify and mitigate bias

Data Collection

"A description of the size of each data set"

Data Annotation

"A description of the expertise of those performing the data annotation"

Independence of Data

"In general, test data should come from sites different from those used to develop the AI-DSF"

DEVELOPMENT

What sponsors should include in a submission?

Model Description

- Model architecture

Model Development

- Optimization Methods
- Training hyperparameters
- Use of ensemble methods

Validation

- Performance
- Usability

"The description of the algorithms and models should be sufficiently detailed to enable a competent AI practitioner to produce an equivalent model."

INTRODUCTION OF AI-DSF INTO CLINICAL WORKFLOWS

CHALLENGES AND GUARDRAILS

Anupama Govindarajan, Ph.D.
Director Regulatory Affairs – Digital Health

J&J MedTech | Heart Recovery

MONITORING RISK IN ALGORITHMS

Concept Drift:

- **Mis-specified model:**

What if there are omitted variables or the estimated function mis-specified?

- **Changing Environment:**

Changes in clinical environment in terms of data fed into a CDS tool

- Data is no longer accessible.
- Underlying data architecture (e.g., EHR) undergoes frequent changes / refreshes

Covariate Shift:

- **Input distribution of new data is different from the training data:**

Is it possible for a CDS tools to learn systemic and structural biases (age, sex, insurance and socio-economic status) and perpetuate these biases?

- **Are the inputs to the algorithm correct as opposed to the inner workings?**

E.g., Data from a CGM compared to that from a blood glucose monitor?

Instability:

- **Do medically similar patients receive medically similar diagnoses or treatment suggestions?**
  - What is the confidence in the output of the algorithm?
  - What happens when there are slight perturbations to the inputs?

Confounding by Medical Intervention:

Did the HCPs act on the algorithm's recommendations?

What actions (external to the algorithm's use) were performed that might have influenced outcomes?
(e.g., early action, additional treatments, temporal information that could have influenced the care pathway).

CONTROLS AROUND INTEGRATING AI/ML WITH CLINICAL WORKFLOWS

Joint Responsibility of Manufacturers and Implementers: Clinical Governance & Oversight

- Alignment among the intended use & purpose of the AI-DSF & expected clinical impact
- Representativeness of the training dataset and validation methodology in relation to the patient population that the AI-MD would be used for
- Any known patient safety issues with the AI-DSF on the global market
- Risks of implementation: Ability to switch back to fully human care or earlier validated AI pathways

POST-MARKET CONTROLS – AI/ML ALGORITHMS

Performance at or above deployment baseline with appropriate triggers and escalation pathways if the AI-DSF's performance falls below baseline

- ❑ Identify key monitoring outcomes and monitoring frequency
- ❑ Select input and output thresholds for these outcomes

- ❑ Put in place self-validation mechanisms that trigger escalations when thresholds are breached
  - ❑ Initiating human intervention (i.e., "safe fails")
  - ❑ Reverting to an earlier validated pathway
  - ❑ Shutting down the AI-DSF

- ❑ Detect / Respond / Recover from Cybersecurity vulnerabilities / attacks
- ❑ Regular performance reviews and annual cybersecurity penetration testing of the AI-DSF

- ❑ Device issues resulting from the use of the AI-DSF
  - ❑ Immediately respond: Contingency plans should include shutting down the AI-DSF and switching to analog protocols
  - ❑ Investigate and Understand:
    - ❑ Model drifts,
    - ❑ Datasets representative of the current patient population
    - ❑ Changes in clinical care
    - ❑ Patient Demographics

SUMMARY

GENERAL CONCERNS WITH THE DRAFT GUIDANCE

One size fits all

- Overly prescriptive
- Broad scope

Redundant

- Other QMS/QSR requirements
- Guidance Documents

Performance Monitoring

- 510k special controls guidance
- Not risk based

Labeling

- Overly prescriptive
- Redundant requirements