

FDASIA Committee Background

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Defining Characteristics

1. User type
2. Phases of product lifecycle
3. Developer/ 'Manufacturer' Type
4. Distribution model
5. Conditions of use
6. Intended use
7. Product categories
8. Miscellaneous

User Types

In Scope

- Health Care Providers – institutional and individual
- Clinical Researchers using on human subjects
- Patients under care by a provider
- General public user/consumer under own use/health management

Out of scope

Product Lifecycle

In Scope

- **Design phase**
- **Testing**
- **Implementation-
Installation**
- **Maintenance &
enhancement**
- **Availability-Downtime
Hazard**
- **Recall**
- **Retirement**

Out of Scope

- **Methods and modes of end-
user training**

Developer/ 'Manufacturer' Types

In Scope

- Entity which develops, markets, licenses, or distributes products with commercial interest
- Entity which develops, advertises or distributes via public channel products intended for general public users, even if no commercial interest
- Healthcare provider* who develops products *de novo* for use on patients, even if no direct or indirect commercial interest
- Healthcare provider* who modifies functionality of previously licensed, 'finished' products

Out of Scope

- Individual who develops for personal private use
- Individual who develops/distributes via private channel to limited individuals without commercial interest

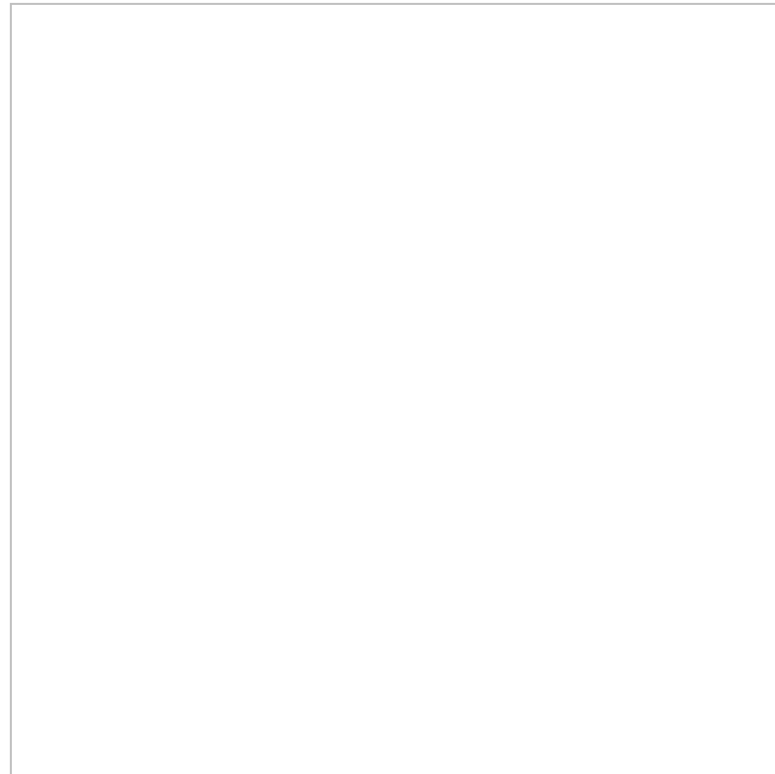
*institutional or individual provider

Distribution Model

In Scope

- Marketed-licensed-distributed-sold in a restricted manner, with credentialing requirements
- Marketed-licensed-distributed-sold in a restricted manner, without credentialing requirements
- Made available for download via an unrestricted public channel, with or without credentialing requirements
- Available under a SaaS model

Potentially Out of Scope



Conditions of Use

In Scope

- By prescription, recommendation or under direction of licensed/credentialed healthcare provider
- Independently by general public consumer/user
- For management of defined illness or chronic condition
- For research purposes on human subjects
- Intended use
- Foreseeable misuse (e.g. interface lacks forcing functions to preclude double entry)

Out of Scope

- For health maintenance or fitness
- Non-foreseeable, willful misuse
- Use clearly beyond labeled intended use

Products Types - Categories

In Scope

- EHRs (installed, SaaS)
- Hospital Information Systems-of-systems
- Decision support algorithms
- Visualization tools for anatomic, tissue images, medical imaging and waveforms
- Health Information Exchanges
- Electronic/robotic patient care assistants

Out of Scope

- Claims processing
- Health benefit eligibility
- Practice management / Scheduling / Inventory management
- General purpose communication tools (e.g., email, paging) used by health professionals
- Population management tools
- Software using historical claims data to predict future utilization/cost of care
- Cost effectiveness analytic software
- Diseases severity scoring algorithms
- Electronic guideline distribution
- Disease registries

Miscellaneous

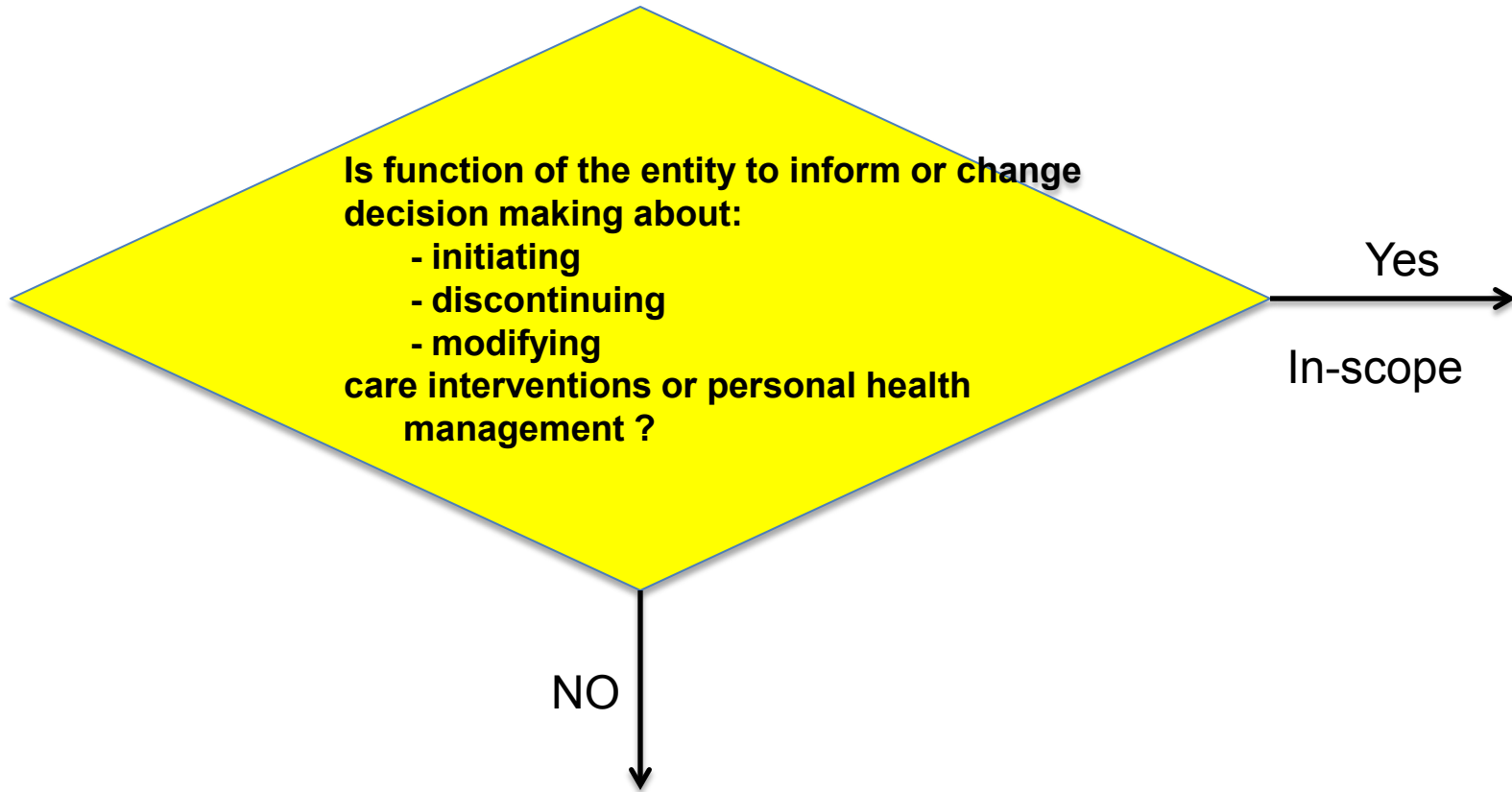
In Scope

Out of Scope

- Regulation around Privacy (HIPAA)

Functionality – Potential for Harm

**DECISION TREE APPROACH FOR
DETERMINING WHETHER OR NOT AN
ENTITY REQUIRES RISK-BASED
REGULATION**



Out-of-scope ...
defer to existing regulatory
framework

Does malfunction, foreseeable misuse have potential to cause patient injury, via:

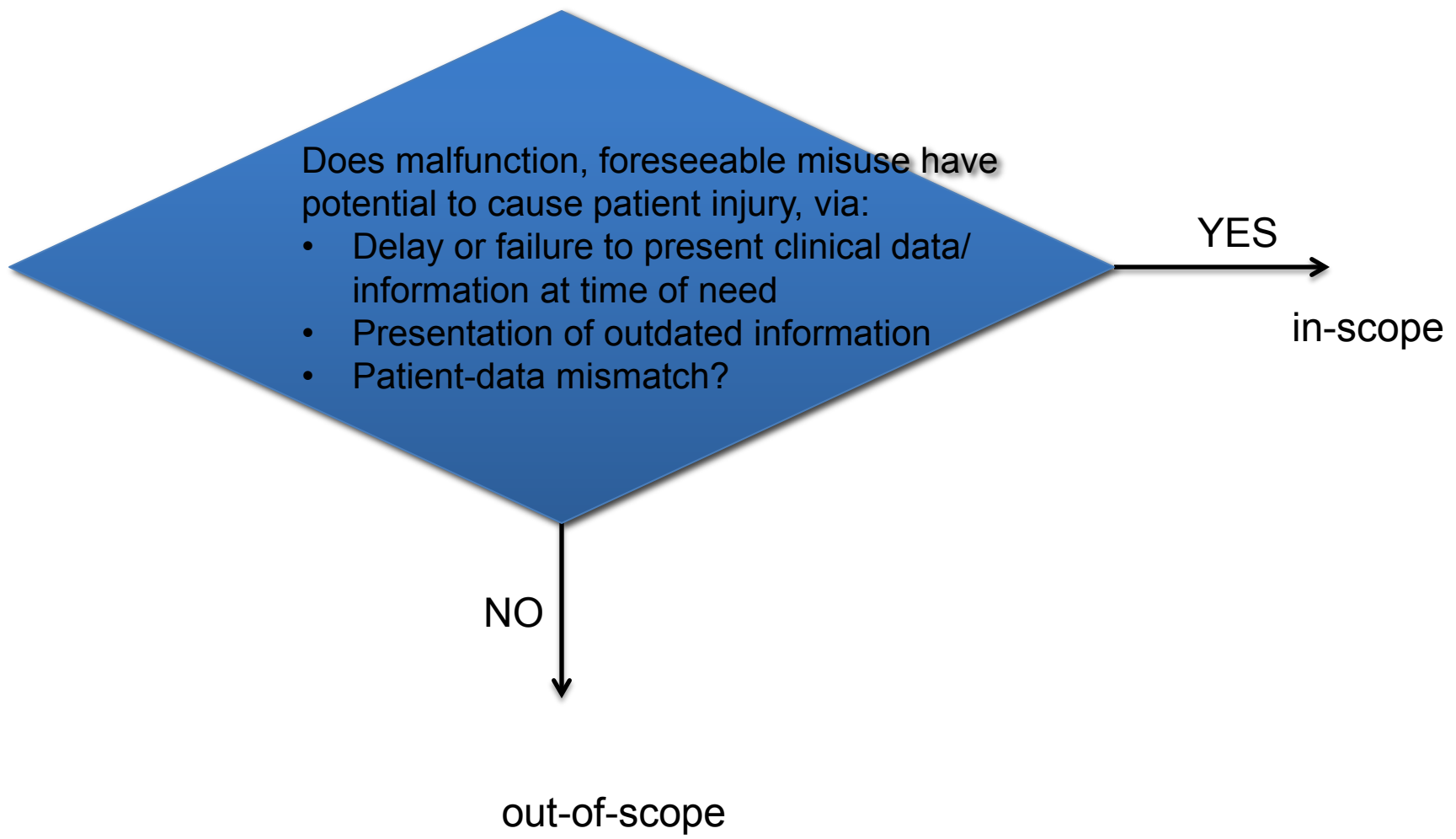
- Delay or failure to present clinical data/ information at time of need
- Presentation of outdated information
- Patient-data mismatch?

YES

in-scope

NO

out-of-scope



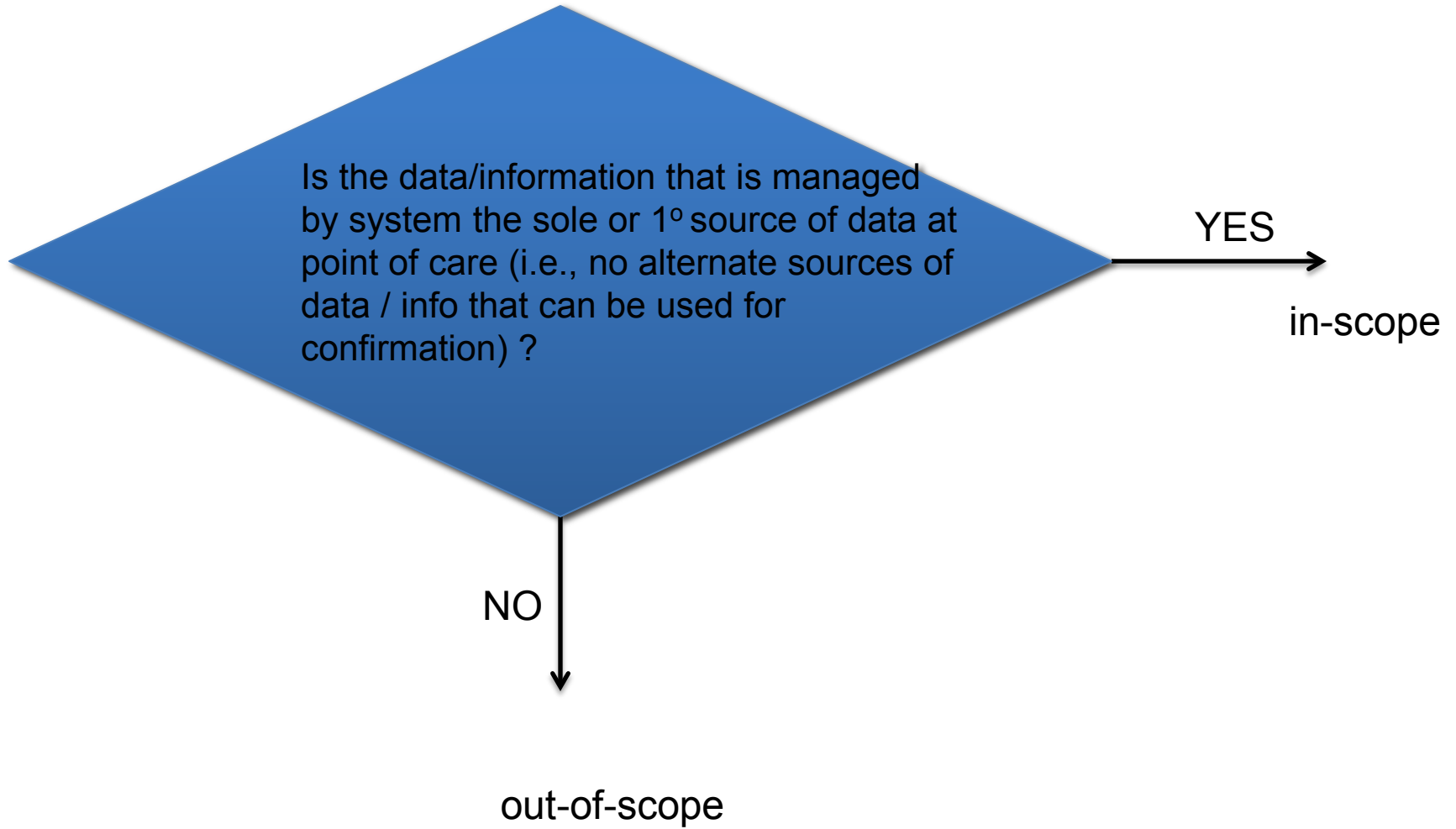
Is the data/information that is managed by system the sole or 1^o source of data at point of care (i.e., no alternate sources of data / info that can be used for confirmation) ?

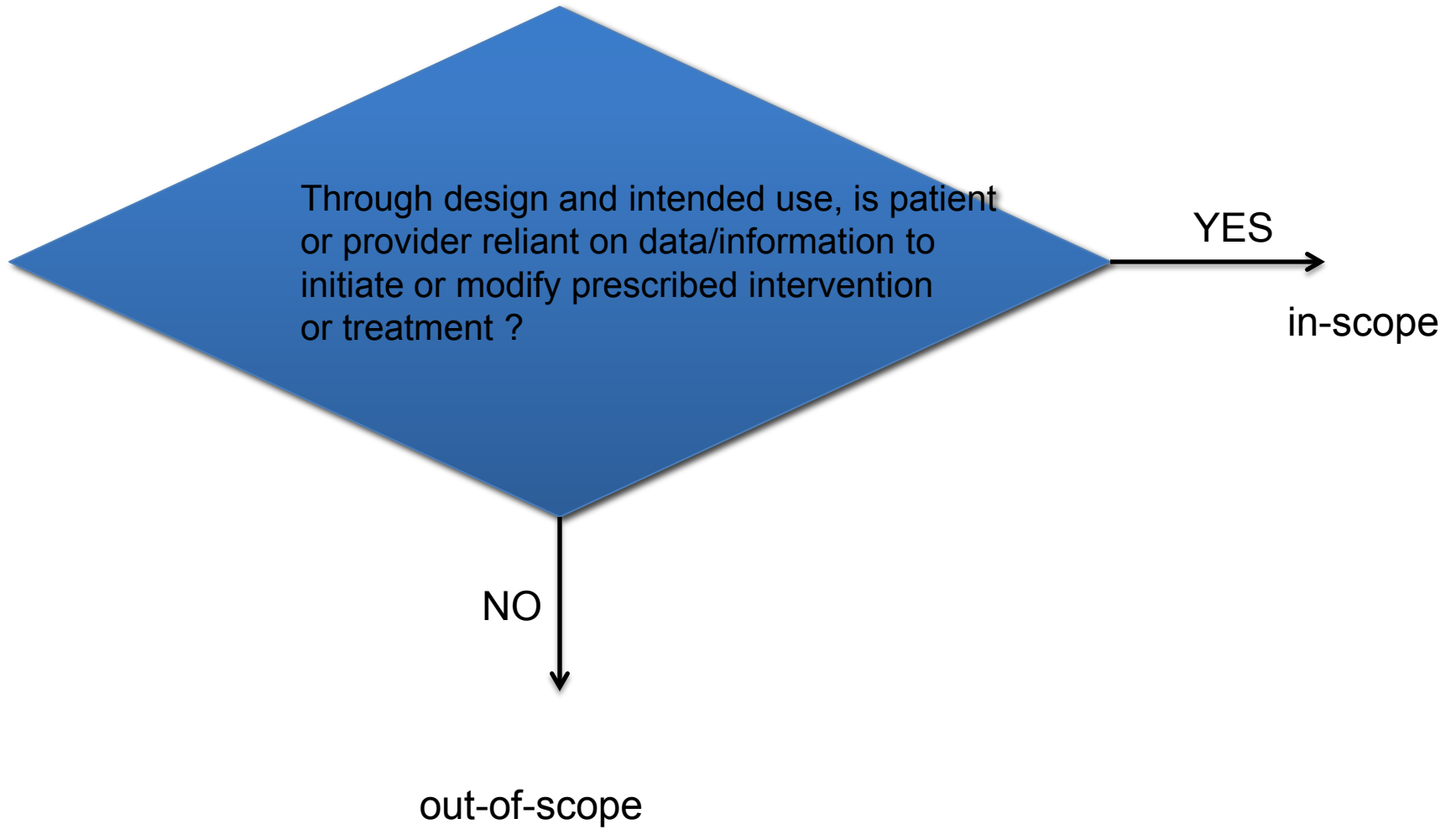
YES

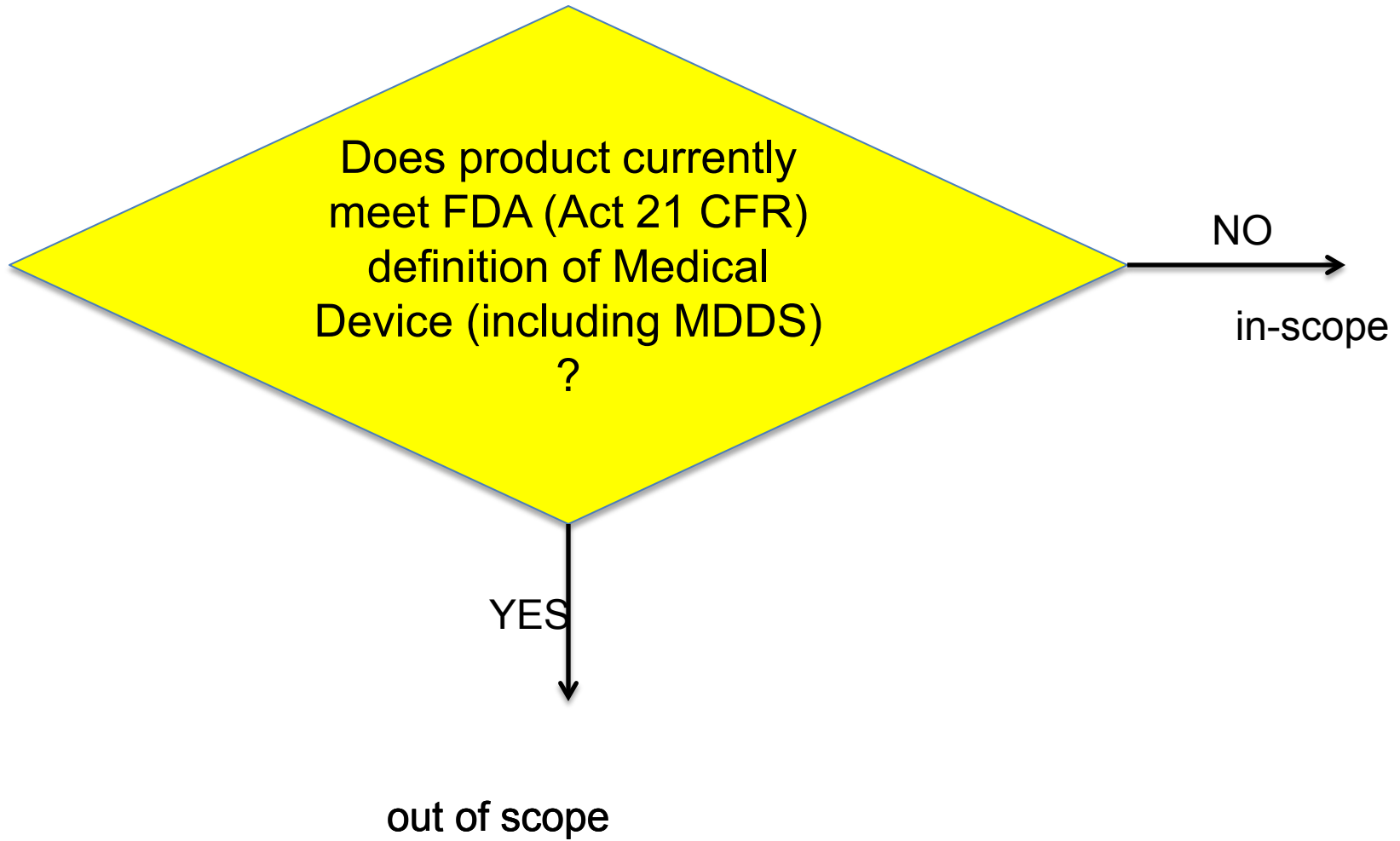
in-scope

NO

out-of-scope







Sample Use Cases

- A psychologist creates a mood-tracking app and provides it free of cost to her patients
 - *Does not require from risk-based regulation*
 - *Requires professional oversight to make treatment decisions, distributed in private channel*
- Rehabilitation specialist develops and sells a electronic coaching aid (sensor-embedded exercise band) for monitoring post-stroke range-of-motion exercise performance remotely
 - *In-scope for risk-based regulation*
 - *Function is independent of clinician oversight, risk of misuse is high*
- Hospital's IT services modifies a drug-drug interaction app that overlays the institution's EMR
 - *In-scope for risk-based regulation*
 - *Part of the systems lifecycle; recommends treatment decisions*

Summary

- Taxonomy guides the assignment of HIT innovations into two categories: “Requires for Risk-based Regulation” or “Does not require risk-based regulation”
- HIT innovations described by 8 characteristics
- Decision tree guides assignment based on function and potential for harm