Best practices for developing AI tools in a regulated environment

Alejandro Reti, MD, MBA; Chief Medical Information Officer, Optum Technology

Judy Fujimoto, MD, MBA; National SVP Clinical Advocacy and Support

OPTUM Labs®

Disclosures

Financial Disclosures:

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- Judy Fujimoto - None

Outline

1. Why regulation exists – The ‘spirit’ of regulations
2. Key regulatory concepts relevant to clinical analytics and AI
3. Development in a regulated space – Best practices

FDA – Core mission of safety and effectiveness

- Intended for use in diagnosis, treatment, cure or mitigation of diseases or conditions
- May alter the structure or function of the body but does not require a metabolic or chemical reaction to function
- Medical device may be physical components or software/digital functionalities

Three major elements of determining medical device designation

These elements help define if it is a medical device as well as its potential classification

Functions

- What functionalities are embedded in the device?
- Does it interact or control other regulated devices?

Intended Use and Indications for Use

- What is the device intended to do (e.g., real-time vs. trend monitoring)?
- What are the indications for use (e.g., Type II diabetes)?

Risk to Patients/Consumers

- What is the risk to patients if the device were to malfunction?

FDA device classifications

Highest Risk ⟵ ⟶ Lowest Risk

	Class III	Class II	Class I	Discretionary Enforcement	Not a Device
Medical Device	Yes	Yes	Yes	Yes	No
Required to Comply with	• General controls • Premarket approval	• General controls • Special controls • Premarket notification 510(k)	• General controls	*Discretionary enforcement:* • Meets the definition of medical device BUT the FDA does not intend to enforce compliance with regulations	• Functionality and intended use does not meet the definition of a medical device • No requirements to comply with FDA regulations
Examples	• Pacemaker • Coronary stents	• Glucometers • BP cuffs	• Tongue depressors • Scales	• Low-risk mobile medical apps, device CDS	• General wellness mobile apps, MDDS*, non-device CDS

*Medical Device Data Systems

Clinical decision support (CDS) software – A device or not?

CDS software: Intended to provide decision support for clinicians for the diagnosis, treatment, prevention, cure or mitigation of disease or other condition

- MAY NOT meet the definition of medical device. However, certain functionalities and intended uses MAY make it a medical device and under FDA regulatory oversight

Not a Medical Device (must meet all 4)

1) Displays, analyzes, or prints patient medical information or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines)
2) Is intended to support or provide recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition
3) Is intended to enable a health care professional to independently review the basis for the recommendations and the health professional does NOT rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient
4) Is not intended to acquire, process, or analyze a medical image or a signal from an *in vitro* diagnostic device or a pattern or signal from a signal acquisition system

Could Be a Medical Device

1) Analyzes or manipulates radiological or patient images or physiological signals to monitor, diagnosis or aid in treatment of patient
2) Uses undisclosed or proprietary algorithm to recommend treatment or diagnosis

Pulling information together – Establishing likely regulatory status

Best practice #1 – Have an exploratory discussion with counsel / regulatory expert *early* in the concept ideation process

- Is the software involved in the delivery of everyday care, or is it purely management-related and after-the-fact analysis or reporting?
- If it is involved in delivery of care, is that care being delivered by doctors and nurses in the provider setting, or is it being offered by a service delivered by a health plan?
- Is it generating alerts or signals in real time (probably a class II) that are intended to drive care actions (a class III)?
- Does the software include any algorithms that look or feel like a ‘black box’ to make decisions or recommendations?

Don’t look for a decision – Understand the likely situation so you create the rest of your product and AI design accordingly

What should you bring to this meeting?

- Have a clear vision for what you are building. Generalities are only modestly helpful
- They will need very specific information about how it will be used, who will use it, and exactly what data those people have at their disposal when they do their job and how they make decisions
- Mock-ups are almost essential because they will show information and nuances that are very hard to describe otherwise
- Understand the choices you have with your design so you can discuss them
  - For example: How would you display the recommendation alongside the source data?
  - If you wanted to put a ‘human in the loop’ how would you do it?

Designing to minimize regulatory burden

Best practice #2 – Evolve the idea to the lowest feasible regulatory class possible

- Not all use cases require features that invoke regulatory oversight. Time to market, development costs, and maintenance burden with always be lower with a lower level of regulation
- Some key principles here:
  - Value-added analytics should be incorporated only if they really add value
  - Include access to source data so clinicians can see relevant inputs and make their own decisions, as necessary. Don't make any source data inaccessible
  - Design workflows with flexibility. Sometimes the ability to 'lock down' configurable choices will help you get quicker approval
    - Other times, allowing users to make configurations will help you get approved

Developing with rigor demanded of the regulatory classification

Best practice #3 – Fulfill documentation requirements that might be needed for any regulatory filings

- Understand the documentation requirements so the development teams can document ‘as they go’ and don’t have to go back and redo documentation and testing later
- Many of these requirements have to do with testing – Ensuring the algorithms and system those algorithms reside within behave consistently and reliably under all circumstances
- Many also require retaining documentation, including test results. Consult early with counsel to understand what is required from the start

Use case analysis: AI-enabled patient assessments

Use case:

- Patient assessments are often pre-built templates with many questions across a large domain of clinical, and sometimes non-clinical, topics
- Clinical staff using them often consume substantial time completing assessments even though, in many cases, some of the clinical topics are not relevant to all patients
- In other words: For any given patient, assessments are too detailed in some areas and not detailed enough in others. And for all patients, disproportionate time is spent completing these assessments

AI-enabled patient assessments – Important regulatory constraints

1. **State Medicaid programs** often dictate very specific rules for what must be included in a patient assessment as a condition for qualifying for Medicaid state funding
2. **Medicare** includes some additional rules that are less strict but still necessary to comply with, if the solution will be used to manage patients on Medicare
3. **The FDA** will be a consideration, if the design of the assessment (particularly decisions to dynamically include or exclude specific questions) could impact a clinician's ability to diagnose disease or illness
4. Increasingly, **Departments of Justice** are paying attention to the role of technology and algorithms in perpetuating inequity – The algorithms must be carefully evaluated for any differential impact to assessment content across protected classes
5. **Mental health parity** – If the solution meets certain criteria, it must be made available in the behavioral health space as well as the medical side

Example: Dynamic content generation