IQVIA

Regulatory Assessment Tool for Clinical Decision Support Software

A changing regulatory landscape

Clinical Decision Support (CDS) Software can help healthcare providers make treatment decisions and interpret patient data. The increasing development of CDS tools with AI-functionality have spurred the US FDA to develop new regulatory frameworks around the oversight of AI driven software used as medical devices. However, the agency's newest guidance on CDS tools leave a lot of questions for clients as they try to make sense of, and comply with, regulations.

Regulatory challenges

Industry faces certain challenges when complying with regulations and FDA guidance:

"Is my CDS software a medical device?"

Not all AI-enabled software is considered a medical device and, therefore, subject to FDA's jurisdiction.

"What regulations apply to my software?"

Multifunctional devices, including both mechanical functions and software functions, are subject to multiple FDA regulations and policies.

"How do I use RWD for validating my software?"

The real-world data required for AI-enabled device validation and evaluation is uncertain, notably when creating developing proprietary algorithms.

"What FDA pathway do I use?"

Choosing and navigating the appropriate regulatory pre-market pathways can prove challenging with a lack of appropriate predicate devices and cleared analogs to leverage.

Early regulatory strategies and decision-making can help software manufacturers anticipate and navigate barriers to FDA market authorization for AI-enabled CDS tools

CDS regulatory assessment tool

CASE STUDY

IQVIA assessed the regulatory considerations for an AI-enabled clinical decision support (CDS) tool and outlined the regulatory strategy.
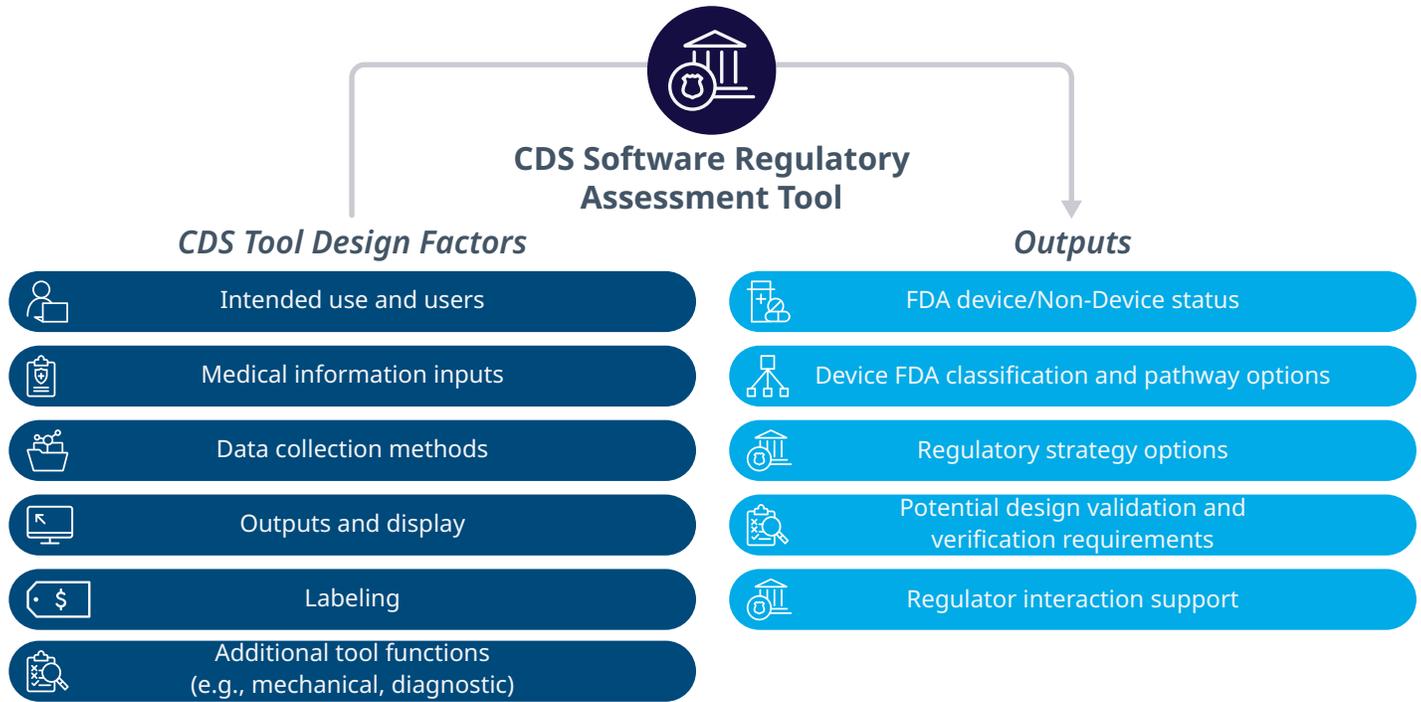
Methods

By reviewing the regulatory landscape, including analysis of similar commercially available devices in the US, synthesized the regulatory strategy options.

Results

IQVIA provided considerations for the regulatory classification of and standard regulations of the CDS tool while also outlining tailored regulatory strategy options including risks, advantages, and disadvantages.

The **CDS Software Regulatory Assessment Tool** analyzes FDA-cleared software, FDA regulatory policies to determine a software's medical device status, inform regulatory strategies for CDS tools, analyze regulatory pathway options.

CDS Software Regulatory Assessment Tool

CDS Tool Design Factors

- Intended use and users
- Medical information inputs
- Data collection methods
- Outputs and display
- Labeling
- Additional tool functions (e.g., mechanical, diagnostic)

Outputs

- FDA device/Non-Device status
- Device FDA classification and pathway options
- Regulatory strategy options
- Potential design validation and verification requirements
- Regulator interaction support

Regulatory expertise

The RSSI team consists of ex-regulators, consultants, and scientists

- 12 regulatory science professionals across the US with experience in RWE policy

- > 17 years of direct US FDA experience

- > 25 years of regulatory experience

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