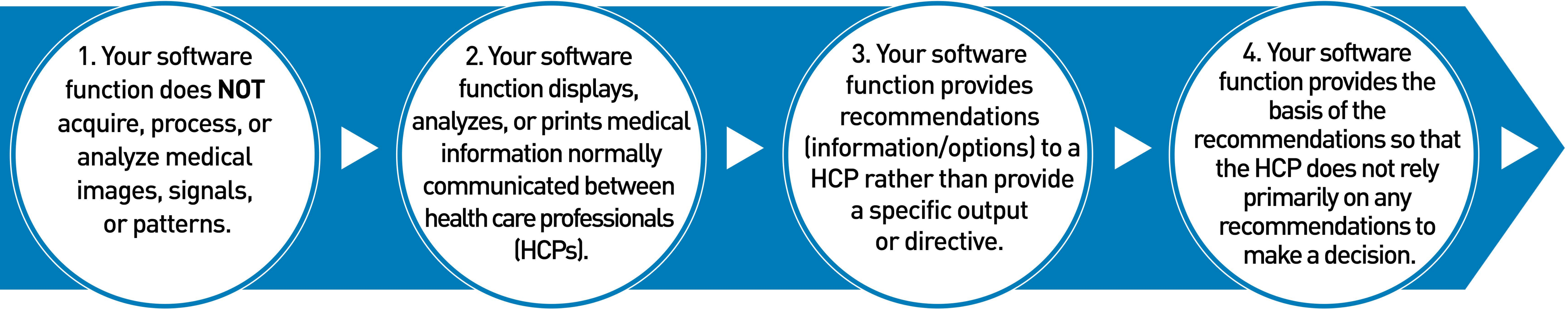


Your Clinical Decision Support Software: Is It a Device?

The FDA issued a guidance, Clinical Decision Support Software, to describe the FDA's regulatory approach to Clinical Decision Support (CDS) software functions. This graphic gives a general and summary overview of the guidance and is for illustrative purposes only. Consult the guidance for the complete discussion and examples. Other software functions that are not listed may also be device software functions. *

Your software function must meet all four criteria to be Non-Device CDS.

Summary interpretation of CDS criteria



Your software function may be non-device CDS.

Non-Device Examples

- Non-Device examples display, analyze, or print the following examples of medical information, which must also not be images, signals, or patterns:**
- Information whose relevance to a clinical decision is well understood
 - A single discrete test result that is clinically meaningful
 - Report from imaging study
- AND**
- Non-Device examples provide:**
- Lists of preventive, diagnostic, or treatment options
 - Clinical guidelines matched to patient-specific medical info
 - Relevant reference information about a disease or condition
- AND**
- Non-Device examples provide:**
- Plain language descriptions of the software purpose, medical input, underlying algorithm
 - Relevant patient-specific information and other knowns/unknowns for consideration

Device Examples

- Device examples acquire, process, or analyze:**
- Signal acquisition systems
 - In vitro diagnostics
 - Magnetic resonance imaging (MRI)
 - Next Generation Sequencing (NGS)
 - Continuous Glucose Monitoring (CGM)
 - Computer aided detection/diagnosis (CADe/CADx)
- OR**
- Device examples display, analyze or print:**
- Continuous signals/patterns
 - Medical images
 - Waveforms (ECG)
 - More continuous sampling (aka – a signal or pattern)
- OR**
- Device examples provide:**
- Risk scores for disease or condition
 - Probability of disease or condition
 - Time-critical outputs
- OR**
- Device examples:**
- Basis of recommendations is not provided

Your software function is a device.

*Disclaimer: This graphic gives a general overview of Section IV of the guidance (“Interpretation of Criteria in Section 520(o)(1)(E) of the FD&C Act”). Consult the guidance for the complete discussion. The device examples identified in this graphic are illustrative only and are not an exhaustive list. Other software functions that are not listed may also be device software functions.