Clinical Decision Support Software Proposed FDA Regulatory Framework Webinar

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Clinical Decision Support Coalition

Agenda

1. Overview of Clinical Decision Support (CDS) Software
2. CDS Regulatory Framework Walkthrough
3. Use Cases
4. Q&A / Guided Discussion

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Clinical Decision Support Overview

FDA's preliminary Definition is very BROAD

CDS uses patient specific information and converts (via algorithm or other processing) it into patient specific actionable results

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CDS Characteristics

- CDS includes a broad range of products with varying degrees of risk
  - All CDS products should not be treated the same
- Unlike diagnostic medical devices such as imaging or laboratory tests,
  - CDS analyzes, rather than generates, information
  - Thus it simply aids the user in the thinking process
- Need to consider role of the user in mitigating risk
  - CDS users can be patients, healthcare professionals and specialists

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CDS Coalition's Proposal

- ☑ Defines **Clinical Decision Support**
- ☑ Distinguishes between different kinds of CDS products **based upon risk**
- ☑ Proposes that any CDS software where the user is **not substantially dependent** on the software be **unregulated**.
- ☑ Provides **detailed and self-explanatory criteria** to determine if a product is **unregulated**

A risk- based approach that avoids overregulation of low risk CDS while protecting patient safety and promoting innovation

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Coalition's Proposed Regulatory Framework Answers 3 Questions

What is CDS?

Should it be regulated CDS?

If so, how should it be regulated?

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What is CDS Software?

CDS is ***stand-alone*** software that

Uses Information

- Patient specific information, for example
  - ✓ Medical Device Data
  - ✓ Environmental data
  - ✓ Demographic data
- Clinical Content

Performs Analysis

- Via
  - ✓ Algorithms
  - ✓ Formulae
  - ✓ Database look-ups
  - ✓ Rules or associations
- More than mere display or transmission

Produces Clinical Decision

Actionable result that is

- Patient-specific
- Contains a primary recommendation

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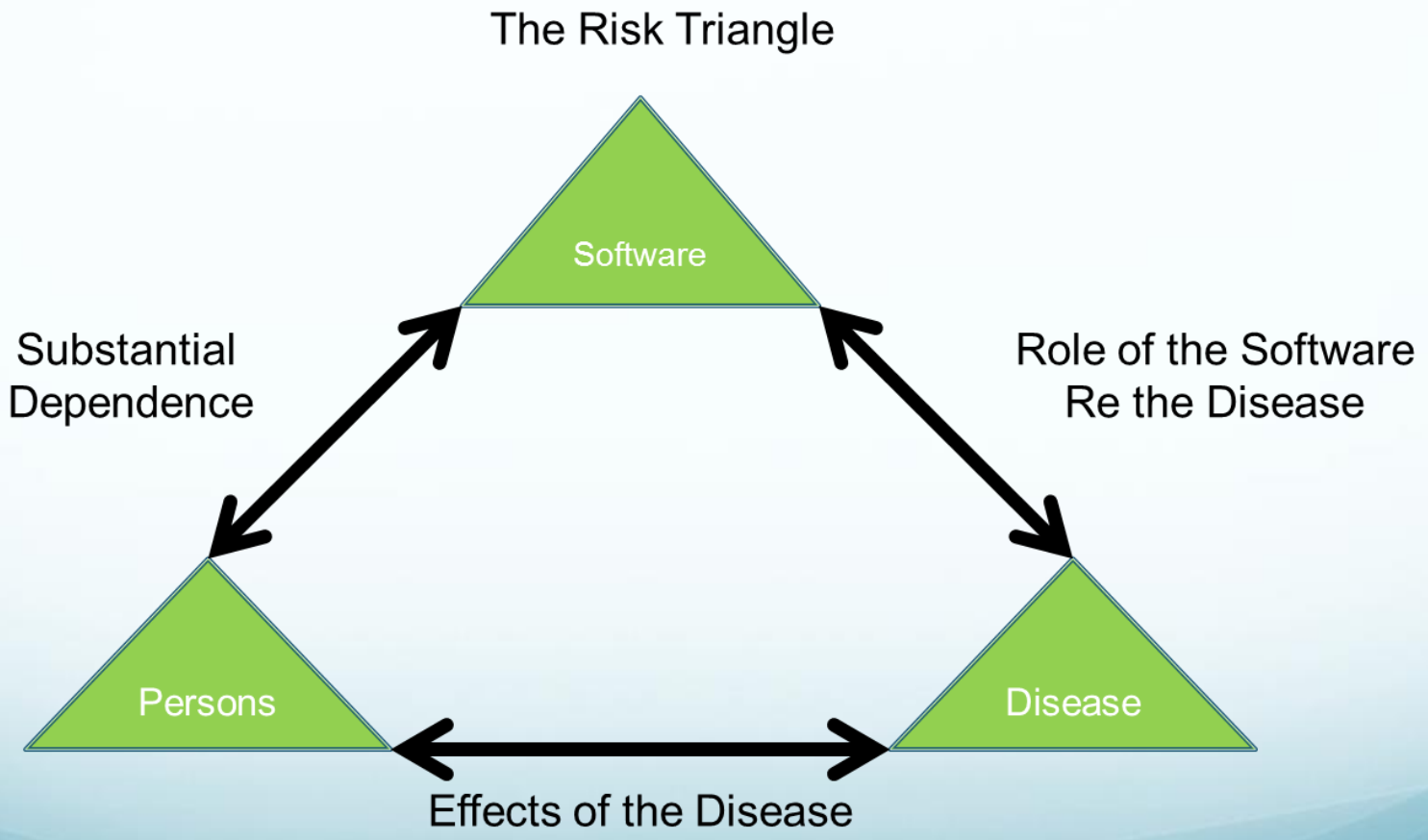
What CDS Software should FDA Regulate?



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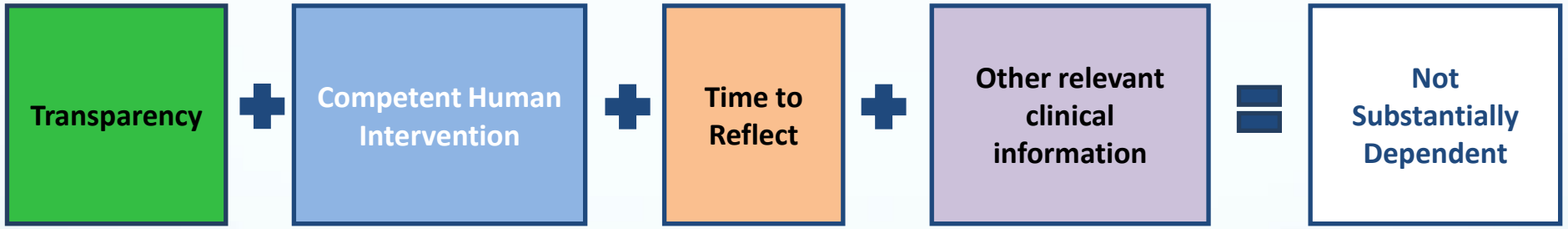
Key distinction between unregulated and regulated CDS:
Is the User ***Substantially Dependent*** on the CDS?



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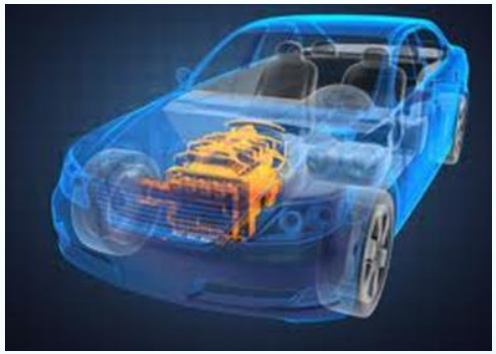
Substantial Dependence

Transparency + **Competent Human Intervention** + **Time to Reflect** + **Other relevant clinical information** = **Not Substantially Dependent**



- Transparency of the CDS:
  - Does the software reveal
    - Its intended use
    - Its inputs, including
      - the underlying data it considered,
      - the source of its clinical analysis, and
    - the context and clinical logic of its recommendation?

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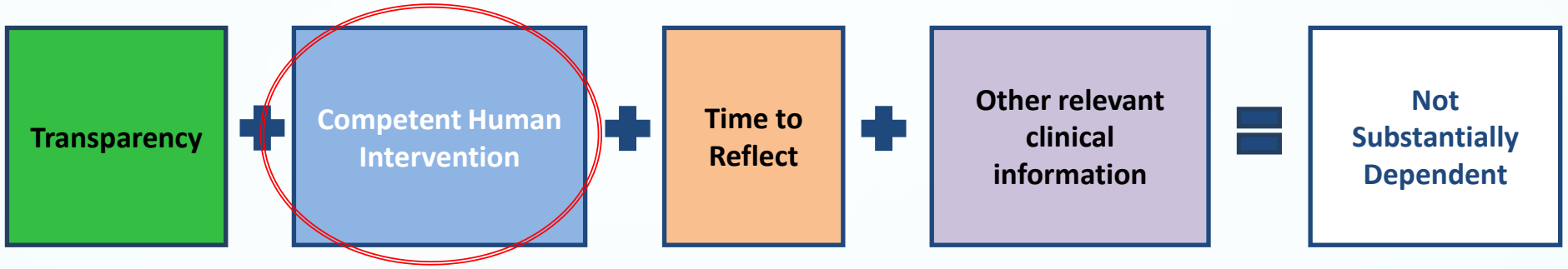
Substantial Dependence



- Competent Human Intervention:
  - Is the user qualified to understand and critically evaluate the software's recommendations?
    - Could the user have made the decision without the CDS?
  - Consider
    - Skill, experience and knowledge of the user
    - Nature of the clinical decision

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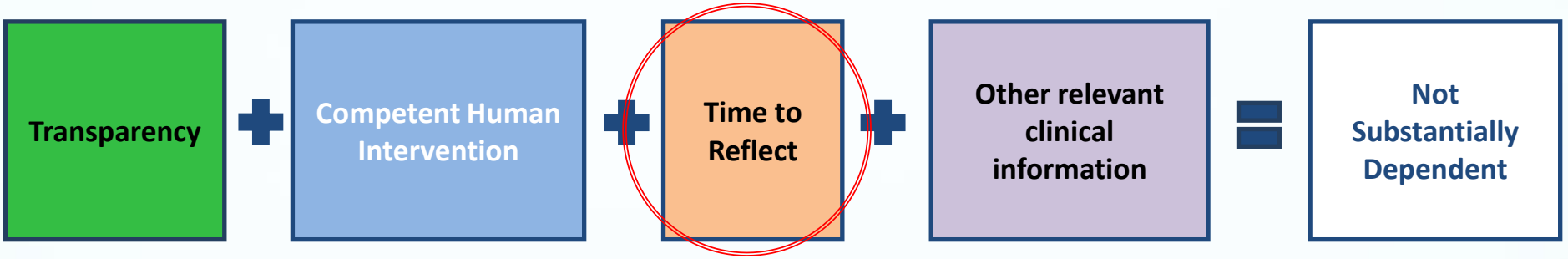
Substantial Dependence



- Time to Reflect:
  - Does the user have enough time to reflect and/or challenge the software recommendation?
  - Consider
    - amount of time available in the anticipated care setting, with the anticipated clinical condition and
    - the complexity of the clinical decision making process.

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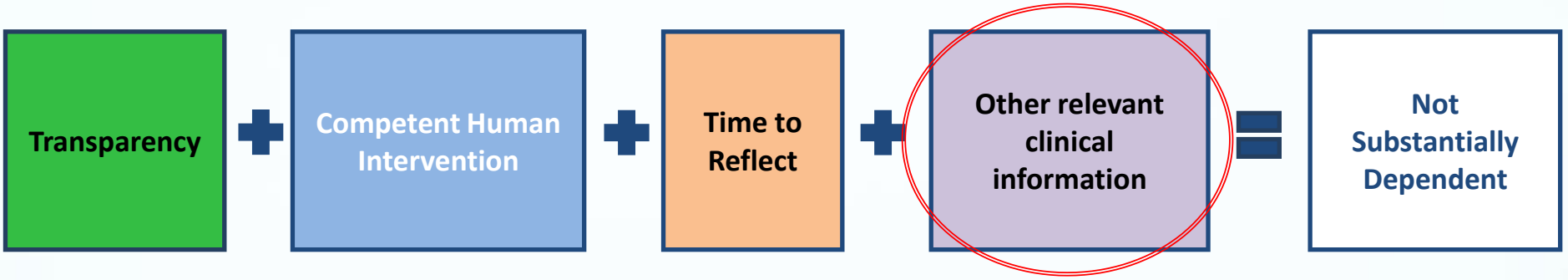
Substantial Dependence



- Availability of Other Clinical Information:
  - Does the user have other clinical information available in making the decision?
  - User needs sufficient additional information to independently arrive at a decision without the aid of the CDS.

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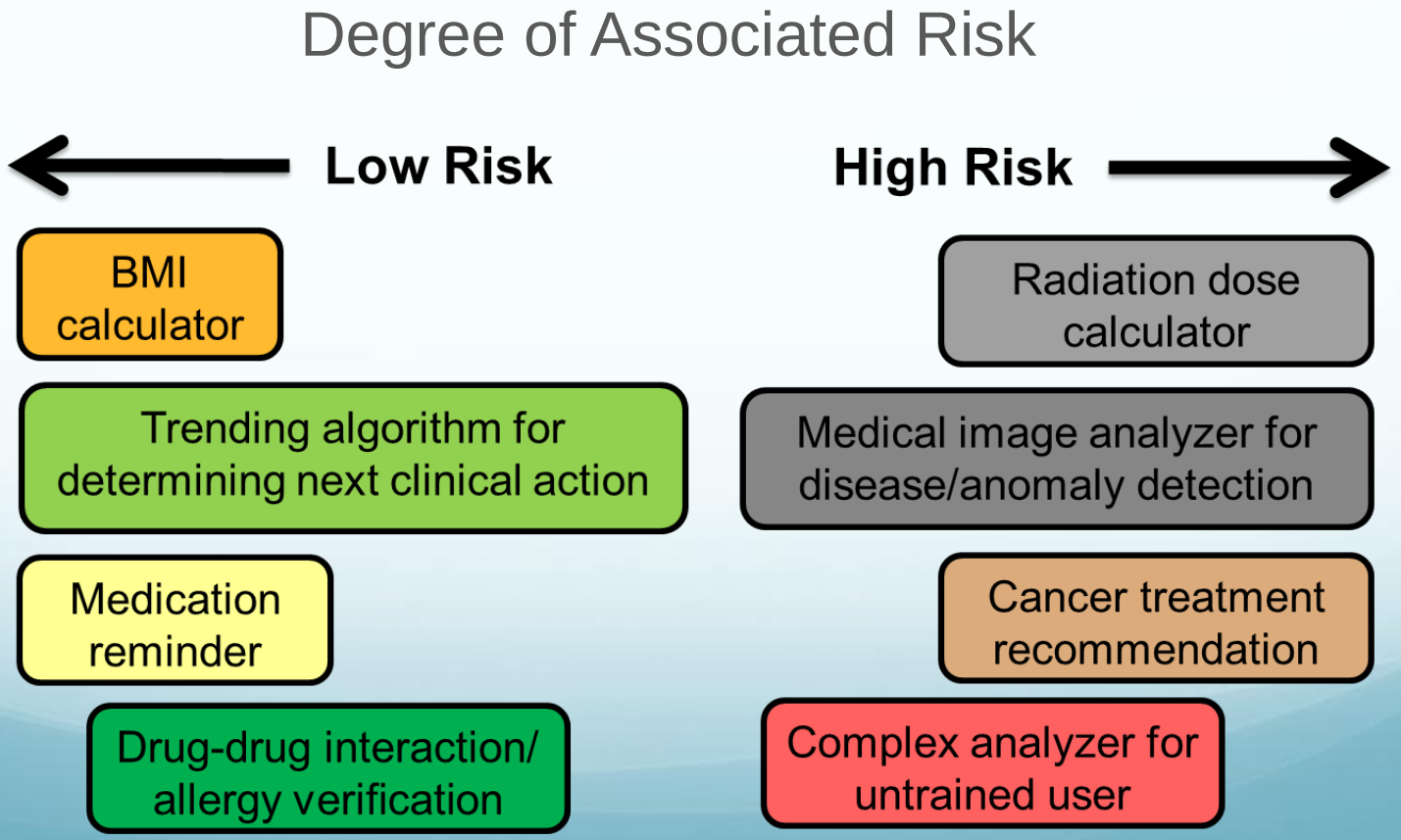
If it is Regulated CDS, how should it be regulated? Risk-Based Regulation of CDS



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Key Factor in Reducing Risk and Regulatory Burden: Use of ***Appropriately Vetted Clinical Content***

- Clinical content that has been approved, published, or sanctioned by an appropriate source.
- Any qualified, peer reviewed journal; a recognized medical or scientific society; government agency or other source that is able to adequately ensure the reliability and accuracy of the information
- Quality and reliability of the underlying clinical content

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Instructions

- For each of the following use cases, we will ask you two questions via a poll:
  1. Would this CDS be subject to regulation under the CDS framework?
  2. Does the use case present safety issues that merit at least some level of regulation?

- The first question is designed to test how clear and useful the coalition's framework is, and
- The second obviously is designed to test whether it produces the right result.

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Is this regulated CDS?

Cancer Clinical Trial Selection Software

- Provides physicians with recommendations for clinical trials for their cancer patients
- Utilizes publically available data on clinical trials and patient specific information entered by a physician to analyze clinical trial options.

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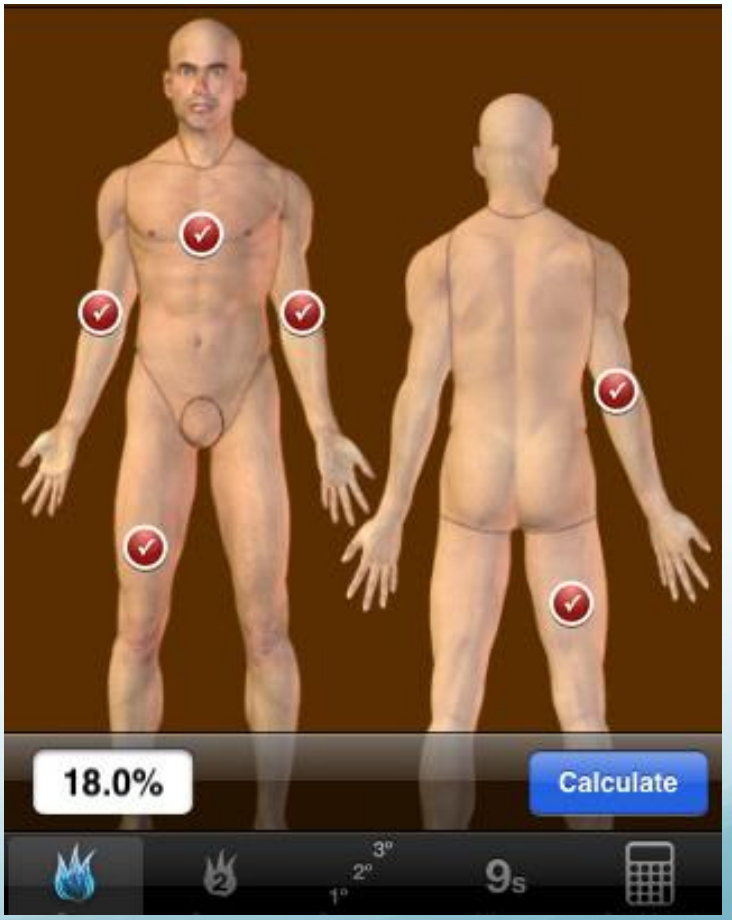
Is this regulated CDS?

Burn Victim Fluids Assessment

- The software utilizes a variety of clinical data (including pictures and video) to perform an analysis of a burn victim
- The software performs a total body surface area to propose emergency treatment options for burn victims
- The calculation method is unknown to the User



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Is this regulated CDS?
Burn Victim Fluids Assessment

- The software utilizes a variety of clinical data (including pictures and video) to perform an analysis of a burn victim
- The software performs a total body surface area to propose emergency treatment options for burn victims
- The software uses the Parkland formula and provides details of calculation to the User

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Is this regulated CDS?

Content and Predictive Analytics Software

- Utilizes all forms of clinical information available to make treatment recommendation
- For use in an emergency care setting
- Identifies novel treatment approaches and rationale is not ascertainable to the User

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Q&A Instructions

- To ask a question “raise your hand” by clicking the hand icon on the side bar of the control panel and your line will be unmuted
- You can also type your question into the box labeled “Questions” and the moderator will read it

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Q&A

- Does the proposed substantial dependence model adequately mitigate any relevant safety issues?
- From the patient's standpoint, does the dependency model capture the relevant risk factors, both for consumer driven software and assure the safety of professional level software?
- From the provider and medical professional perspective, does the dependency model capture the relevant risk factors and offer a practical solution that will ensure appropriate access to CDS?

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Q&A

- From the industry standpoint, does the dependency model create a practical dividing line that would allow industry to proceed with needed innovation?
- Are there other factors to consider when determining substantial dependence? Or when assessing whether CDS is regulated or how?
- Is CDS appropriately defined?
- From a provider and medical professional perspective, are there specific software tools you use that should be included in or excluded from the definition of CDS?

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Q&A

- From the patient's perspective, what oversight would you like to see for CDS products used in your care?
- From a vendor perspective, what factors do you consider to mitigate risk in product development?
- From a provider or patient standpoint, are there other factors that should be considered to mitigate risk in product development?

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Feel free to continue the dialogue by contacting Kim Tyrrell-Knott at KTYRRELLKNOTT@EBGLAW.COM or (858) 764-2494.

Thank you!