

ALLIANCE 1-SLIDE BREAKOUT SUMMARY SLIDE: **SCANNING** SESSION: **1**

Key elements, next steps, timeline

1. Definition
2. Characterization
3. Identify existing phantoms for use (non tissue-based)

Pros for Patient, Clinical, R&D, and regulatory

1. Patient – more companies involved, more innovation, improved safety
2. Clinical – improve QA, more choices for practice of medicine
3. R&D – Innovation
4. Regulatory – simplifies review, speed products to market

Standardized  
characterization  
of digital slide  
scanning (2  
years)

Concerns for patients, clinical,  
R&D, and regulatory

1. Patients – increased risk (unknown critical characteristics)
2. Clinical (same as above)
3. R&D – limits innovation
4. Regulatory – incomplete implementation results in additional burden with no benefit.

Implications and efforts

1. Standardize the inputs – the value is not in the scanning itself, but in the quality of the diagnostic data.
2. Efforts – Very large. A champion and a project manager required. Large discussion body inclusive of as many stakeholders as possible.

ALLIANCE 1-SLIDE BREAKOUT SUMMARY SLIDE: **SCANNING** SESSION: **2**

### Key elements, next steps, timeline

1. Can a set of standard characteristics be determined for digital pathology that cover the measurement space of clinical performance?
2. What is too much variation for AI?
3. Who/how to determine what is too much?
4. Examples where this has happened – Ultrasound, MRU, CT

### Pros for Patient, Clinical, R&D, and regulatory

1. Faster go to market.
2. Faster implementation.
3. Simplified approval process

Elimination  
of clinical  
evaluations –  
an open  
question

### Concerns for patients, clinical, R&D, and regulatory

1. Increased risk to patients if characterization is insufficient or if truth is not correctly defined.
2. Un-true truth will inhibit R&D, regulatory and Clinical implementation.

### Implications and efforts

1. Characterizing a system based upon technical characteristics is cheaper, faster, more objective.
2. How to define a truth that is not based upon human interpretation?