ALLIANCE 1-SLIDE BREAKOUT SUMMARY SLIDE: **PRE-ANALYTICS** SESSION: **1**

Key elements, next steps, timeline

1. Survey (Role/Responsibilities) + 3 months
   a. Pathologists (control slide for imaging)
   b. Histologists/Lab director (control slide for tissue prep)
2. Pre-analytical Prioritization and/or key requirements are identified (Tissue, Imaging, Ground Truth) + 5 months
3. Results feed to Whitepaper/Publications/Guidelines + 9 months

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

1. Guides manufacturers on quality control requirements
2. Interpretative accuracy improved by controlling variability via standards
3. Improved pathologists' concordance
4. Enables the objective assessment of slides across different laboratories
5. Harmonization of efforts across other Alliance projects

Survey Population (4 months)

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

1. Risk to interpretive accuracy if poor data is used
2. Poor ground truth data/imaging sets for innovation/technology development
3. Wrong treatment provided to patient if decision was based on pre-analytical mistakes
4. Garbage in-Garbage Out
5. Don't make it too broad so you don't lose relevance

Implications and efforts

1. Education of impact of pre-analytical variation
2. Guidelines to promote MDDT submissions for pre-analytical standards
3. Quality Control recommendations
4. Whitepaper
5. Guideline for control slide creation

ALLIANCE 1-SLIDE BREAKOUT SUMMARY SLIDE: **PRE-ANALYTICS** SESSION: **2**

Key elements, next steps, timeline

1. Survey (Role/Responsibilities) + 3 months
   a. Pathologists (control slide to imaging)
   b. Histologists/Lab director (control slide for tissue prep)
2. Pre-analytical Prioritization and/or key requirements are identified (Tissue, Imaging, Ground Truth) + 5 months
3. Is pre-analytical standards only applicable to tissue-based knowledge?
4. Results feed to Whitepaper/Publications/Guidelines + 9 months

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

1. Guides manufacturers on quality control requirements
2. Interpretative accuracy improved by controlling variability via standards
3. Improved pathologists' concordance
4. Enables the objective assessment of slides across different laboratories
5. Harmonization of efforts across other Alliance projects

Survey Population (4 months)

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

1. Risk to interpretive accuracy if poor data is used
2. Poor ground truth data/imaging sets for innovation/technology development
3. Wrong treatment provided to patient if decision was based on pre-analytical mistakes
4. Garbage in-Garbage Out
5. Don't make it too broad so you don't loose relevance

Implications and efforts

1. Education of impact of pre-analytical variation
2. Guidelines to promote MDDT submissions for pre-analytical standards
3. Quality Control recommendations
4. Whitepaper
5. Guideline for control slide creation
6. Innovation around QC could create a market/pathway for MDDTs