Open Topic

Key elements, next steps, timeline

- Understanding of what RWD vs RWE is
  - RWD is clinical data – what is generated day to day. This is then **harmonized** (from different locations)/cleaned when you have an intended use to become evidence
- Standards-based data formats, minimum requirements.
- Standardized language and lab reporting is needed and a tangible RS tool
- Least burden to prepare the data

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

- Helpful for the transition of EUA to 510k
- Established best practices – later define statistics behind this
- Could using an exiting LDT within the regular, routine pathologist's workflow be a way to expedite gathering RWD? Does the vendor have the right to use this data? "Triangle" between lab, Vendor, and FDA
- Registries

- Define terms and characteristics around data set types (training, testing, tuning)
- Checklist or position paper with FDA around these terms
- Example of what data set should look like under each term

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

- Is presented data true and accurate?
- Will the RWD gathering process via FDA for approval be so long that the technology is no longer applicable?
- Post-market surveillance issues? Quality assurance/control monitoring

Implications and efforts

- Understand current definitions within PCCP guidance
- Data variability needed will be specific to the question being asked
- These are recommendations
- Collecting data is active work, to be done by humans
- Early adopting labs using LDTs are the generators for much of this RWD

BREAKOUT SUMMARY SLIDE: **Digital Diagnostic Signout** SESSION: **____Wed 12☺)**

Key Elements, Next Steps, Timeline

Create permanent change for Digital Diagnostic signout

- Clarification of post Pandemic Rule
- Codification (Legislation) of new Rule

Definition of "Secure": where do the data reside?

- Where does the lab extend? (Cloud?)

Does this include biomarkers (primary signout)?

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

- Data from digital diagnostic signout:
  - forms the foundation for post-market FDA surveillance, data procurement for health care decision making
  - ensures availability of services, including subspecialties, independent of local constraints
  - Improves quality of service (access to talent, TAT,)
  - promotes R&D, QA

2023

Concerns for Patients, Clinical, R&D, and Regulatory

- Loss professional credibility/compensation via "uberization"
  - Preserve pathologists as members of lab
- Information security, HIPAA restrictions
- Application across pathology spectrum (access across institutions)
- Not-in-good-faith use of "digital diagnostic signout" or malpractice using "it was digital" as an argument.

Implications and efforts

- Facilitates digital access to small and rural programs
- Availability of pathology diagnostic services, including subspecialties, independent of local constraints/
  - Access to Frozen sections, etc.
  - Downstream implication on hospitals (maintain surgical and clinical offerings, keep facilities open)
- Open letter with case studies re: lack of providers/services (pathology RV, no FS, shifts on TAT, number of empty pathology job slots). (backed by data. Source? – no difference in amended reports.)
- Labs would need:
  - "How to implement Remote signout" toolkit
    - Signout location mappings (part of QM)

PCCP

Key elements, next steps, timeline

Design a simple use case (patient population extension, new scanner, etc.) to determine:
-What the end user (laboratories) need to do as a result of CLIA
-What the laboratory would need in the labeling and communication sections of a PCCP.

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

Pros (Patient, Clinical, R&D): Timely updates and ideally improved performance. Faster innovation.
Regulatory: Help the regulators understand what they should be seeking from a manufacture's PCCP to improve clarity to the end users. Identify pitfalls and best practices.

Mock Submission

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

-Concerns: Addresses the concerns of connecting the labortory implementation of the changes made in a PCCP.
-Also addresses, transparency issues since the PCCP document is not intended to be released in its entirety to the public.
Remaining concern of future regulatory issues around marketability of the changes that may or may not occur.
-Cloud based AI tools are going to need laboratories to update at a certain cadence, so they don't have to maintain older tools

Implications and efforts

May surface issues that have not been thought about.
Define what level transparency will be essential for users to know about potential product changes.

- Education for manufactures on what eases labortory implementation
- Education for pathologists on how a product with a PCCP could change overtime and what that means for labortory verification.

PIcc23 – 1-SLIDE BREAKOUT SUMMARY SLIDE: **STATISTICS** SESSION: **2**

Framework for characterizing model variability during the device development and how it can inform validation study

Key elements, next steps, timeline

- Needs **real world data**
- Performance criteria
- Establish **reference standards** during development
- **Pre-development subgroup analysis** to identify covariates

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

- Patient: more **robust devices** cleared that can better handle diverse population
- Regulatory: quicker submission TAT
- R&D: structured study design with **clarity** for what regulatory wants

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

- Patient: Trust that covariate analysis doesn't miss any subgroups
- R&D: more expensive development, more effort to do pre-development subgroup assessments

Implications and efforts

- Subgroup assessments for one use case could help **generalize** for other use cases
- More work required by R&D
- Regulatory is better equipped to deal with submission -> incentivizes industry to use framework