BREAKOUT SESSION

2:45 PM - 3:35 PM

Prepare Your Playbook to Obtain FDA Approval for Your Laboratory Developed Tests

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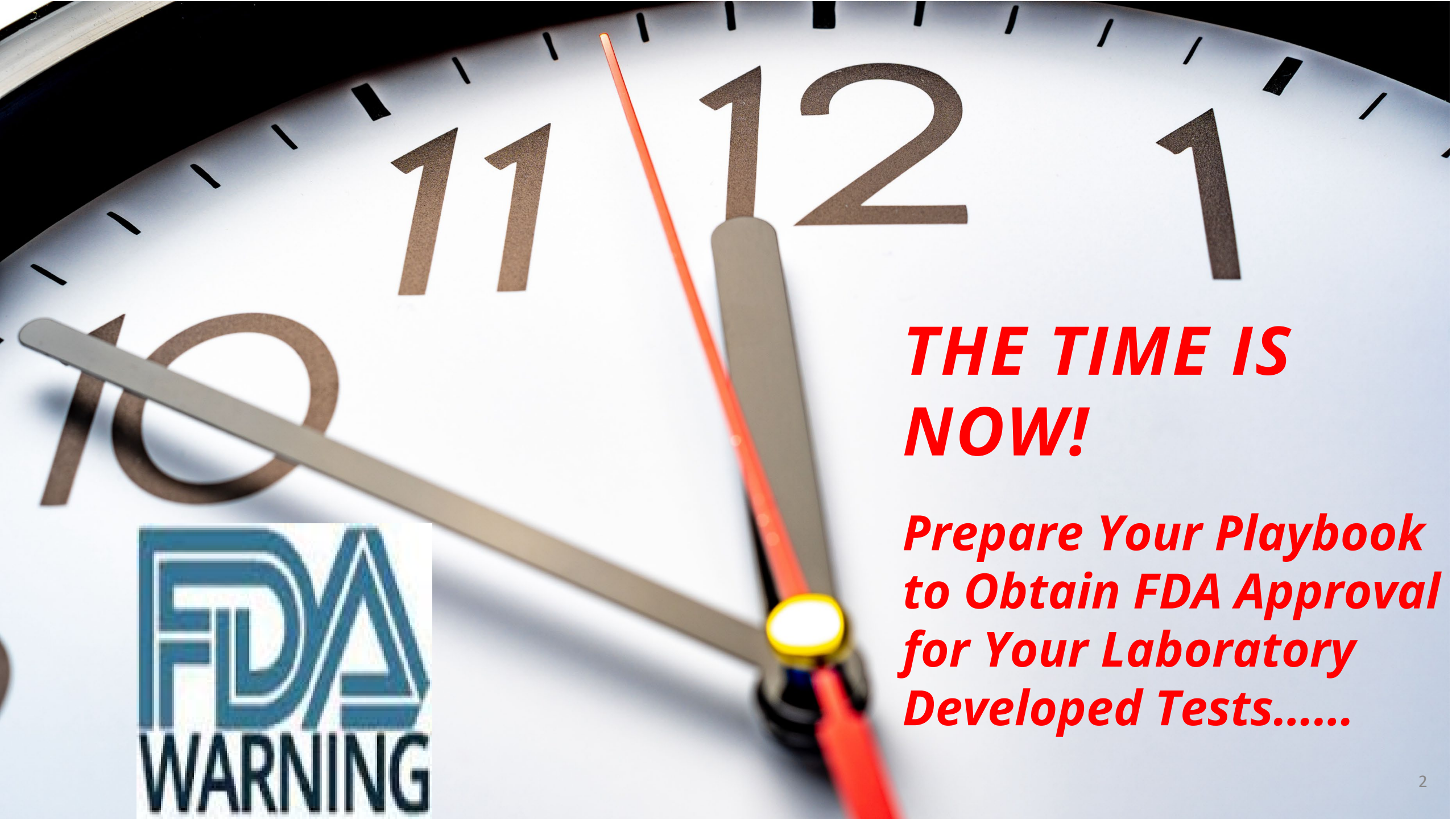

THE TIME IS NOW!

Prepare Your Playbook to Obtain FDA Approval for Your Laboratory Developed Tests……

Agenda

- How did we get here and why? - Jane
- ABC's of compliance – Sheila
- How to operationalize and review financial impact- Valerie
- Summary and Q&A – All

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How Did We Get Here?

FDA Enforcement Discretion:

- ✓ FDA has been indicating its intent to regulate LDTs for the past two decades.
  - 2006 and 2007: Draft Guidance on In Vitro Multivariate Index Assays, never finalized
  - 2010: Announcement of intent to regulate all LDTs
  - October 2014: Draft Guidance, Framework for Regulatory Oversight of Laboratory Developed Tests
  - January 2017: Discussion Paper on Laboratory Developed Tests
  - October 3, 2023: Proposed Rule published
  - April 29, 2024: Final Rule Announced – formal publication expected May 6, 2024

Legislative Activity:

- ✓ Multiple versions of federal legislation proposed and negotiated, but none enacted
  - 2010 – 2015: Better Evaluation and Treatment Through Essential Regulatory Reform Act (BETTER)
  - 2017: Diagnostic Accuracy and Innovation Act (DAIA)
  - 2018 - 2022: Verifying Accurate, Leading-Edge IVCT Development Act (VALID)
  - 2020 and 2021: Verified Innovative Testing in American Laboratories Act (VITAL)

LDT Landscape & FDA Enforcement

CLIA laboratories & LDTs:

- ✓ FDA plans to regulate nearly all LDTs – 4 year phase-out of LDT "enforcement discretion" *…..unless limited exceptions apply*
  - LDTs = "single-site" IVD devices
  - Clinical laboratory = "manufacturer"
  - Laboratory services" (LDTs) = "medical devices"
- ✓ FDA's "Quality Management Systems" (QMS) Rule will apply to most labs/ LDTs
  - Jan. 2024 harmonization - FDA adopted ISO 13485 by reference
  - Required for labs in Stages 1 and 3…..*in addition to CLIA!*

Laboratory SUPPLIERS:

- ✓ FDA already regulates reagents, instruments, software/bioinformatics used in CLIA labs
- ✓ FDA's March 2024 Warning Letter to Agena Bioscience, Inc.
  - FDA's LDT Rule "phase in" enforcement timeline does not apply to lab suppliers
  - FDA WARNING LETTER - Agena Bioscience Inc_Mar.21.2024

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The LDT Rule… .*now FINAL!*

Final Rule includes "grandfathering" and limited carve-outs:

- ✓ Unmodified LDTs marketed prior to May 6, 2024 (e.g., no changes in technology, indications for use or diminished performance)
- ✓ LDTs with NYS-CLEP approval/conditional approval/technical exemption (unmodified)
- ✓ LDTs for "unmet need" furnished by health care facilities to patients receiving care in the same facility (no outside samples)
- ✓ LDTs furnished by the VA and DoD and used in blood establishments

BUT… new FDA requirements apply to virtually ALL LDTs:

- ✓ LDTs marketed before May 6, 2024: Stages 1 & 2, plus FDA QMS requirements for "Records" (make available for FDA inspection); if subsequently "modified" – Stages 1, 2, 3, 4/5
- ✓ NYS-CLEP LDTs – Stages 1, 2 & 3 (includes Records); if modified then Stages 4/5
- ✓ AMCs/hospital labs – Stages 1 & 2, plus FDA QMS requirements for "Records" (make available for FDA inspection); must stay must "be vigilant to determine when LDTs no longer qualify for "unmet need"

AND… FDA is expanding its enforcement resources using Stage 2 listing requirements

- ✓ Stage 2 "listing" requires submission of "labeling;" will include a summary of supporting performance validation data for FDA review to confirm data supports claims
- ✓ Performance summary will be public; FDA anticipates that competitors will "alert [FDA] to potential problems… which will help direct FDA's attention to problematic tests"
- ✓ *Virtually all currently marketed LDTs are required to meet FDA Stage 2!*

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Evolving LDT Regulatory Landscape

FDA's Final Timeline for LDT to IVD Transition

May 6, 2025

- MDR System (Adverse Event Reporting; Correction/ Removal)

May 6, 2026

- Registration & Class-based Listing, Labeling (*includes summary of performance data*) & Investigational Use

May 6, 2027

- Full QMSR compliance for lab and each LDT

Nov. 6, 2027

- PMA submissions for "high-risk" LDTs; mandatory on-site inspections
- ***For each LDT***

May 6, 2028

- FDA submissions for "moderate risk" LDTs
- ***For each LDT***

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LDT Outlook: CLIA + FDA

Industry Expectations.

- ✓ Highly disruptive & costly transition for clinical labs
- ✓ Benefits of grandfathering and carve-outs likley limited

Timing.

- ✓ ISO 13485 Quality Systems requirements by 2027 + FDA submissions by 2028
- ✓ Lawsuits against FDA may or may not delay the compliance timeline

FDA Enforcement.

- ✓ Defending the new LDT Rule is a top litigation priority for the federal government
- ✓ FDA may take enforcement actions against lab suppliers…potential additional disruption
- ✓ "Remote Regulatory Assessment" - New! virtual inspection tool enables wider FDA enforcement

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How to Operationalize and Review Financial Impact- 5 part plan

#1
END IN MIND- STRATEGY

- Do you have an exit plan?
  - IPO/ Strategic exit/ M&A
- Build for high enterprise value + minimize rework

#2- BUILD A 3 YR FINANCIAL MODEL Strategy Today / Exit Strategy Tomorrow

- ID value drivers/ ID Gaps/ ID Lab Differentiators
- ID High enterprise value tests
- Examples: Rare Disease Tests/ Tests with strong IP
- +price reductions + cost increases

#3
OPERATIONALIZE 3 PART PLAN $$$

1. **QMS foundation-** ISO 13485 vs CAP/CLIA requirements - $$
2. **Clinical Data Gaps-** - Specimen Bank, Validation Demographics- **$$$**
3. **Team –** Competency regulatory, stats **$$**

#4
CATEGORIZE TESTS

- High Margin Group
- Export Plan Group
- Import Plan Group

#5
RECONFIRM FINANCIAL MODEL

- **ID Top Risks**
- **+ Upsides**
- **+ Downsides**

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FDA Survival Tips for CLIA Labs

- ✓ ID your transition gaps
- ✓ Learn your risks
- ✓ Act strategically
- ✓ Anticipate burden
- ✓ Don't delay!

RECEIVE A HIGH LEVEL LDT TRANSITION CHECKLIST COURTESY OF

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https://www.surveymonkey.com/r/LDTTransitionChecklistSurvey

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