CLINICAL LAB 2.0

A PROJECT SANTA FE FOUNDATION INITIATIVE

Pathology Informatics-Artificial Intelligence Committee

Committee Co-Chairs: Amjad Azizi, Ulysses Balis
PSFF Board Liaison: Myra Wilkerson

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Pathology Informatics-AI Committee Mission Statement:

Enhance public health outcomes and confidence in laboratory services by leveraging artificial intelligence (AI) for proactive healthcare interventions and integrated diagnostic support.

Create a unified public health infrastructure that uses predictive analytics, early detection, and personalized health interventions to improve population health and reduce costs, while maintaining a strong emphasis on diagnostic stewardship.

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Pathology Informatic-AI Committee: 9 step Business Canvas

Partnerships
- Health Economist
- Public Health Agencies
- Medical and Diagnostic Laboratories
- Payers
- Educational Institutions
- Integrated Health Systems
- Association for Pathology Informatics
- Australasian Institute of Digital Health

Activities
- Public Awareness Campaigns
- Development and validation of AI Models
- Integration of Laboratory and Diagnostic Systems
- Development of Curriculum and Training Programs in use of Lab-based AI
- Identify Public Health Gaps

Key Resources
- Data Science Expertise
- Clinical Knowledge
- Integrated Health IT Systems
- Public Health Knowledge Base
- AI Infrastructure

Value Propositions
- Real-Time Data and Predictive Analytics
- Early Detection and Diagnostics Support
- Enhanced Stewardship
- Risk Stratification and Targeted Interventions
- Actionable Intelligence
- Creation of strategically identified public health repositories of primary Lab data needed for AI-based algorithm development and continued stewardship

Customer Relationships
- Healthcare Systems & Labs
- Government and Community Organizations
- Payers and Health Networks
- Training and Support
- Public-at-large ombudsmen

Channels
- Government Healthcare Channels
- Academic Outreach
- Payers
- Healthcare Conferences and Public Demonstrations

Customer Segments
- Public Health Systems
- Healthcare Networks
- Medical Laboratory Professionals
- Educational Institutions
- Payers
- AI-Centric Lab Instrument Vendors

Cost Structure
- Development and Integration Costs
- Training and Education
- Data Stewardship
- Pilot Programs
- Outreach and Communication

Revenue Stream
- Public Health Funding
- Insurance Reimbursements
- Subscription-Based AI Tools
- Education and Training Programs
- Collaborative Research Grants

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Why Informatics & AI is of Critical Importance to Clinical Lab 2.0

- The clinical inflection point
  - Labs generate the most frequent, longitudinal, and standardized clinical data stream
  - Today: data is mostly used for confirmation after symptoms or downstream clinical concern
  - Tomorrow: data becomes an early-warning system for emerging risk
- Committee purpose
  - Translate CL 2.0 vision into implementable informatics and AI-enabled capabilities
- Core thesis
  - Convert results into actionable intelligence that drives earlier detection, prevention, and lower total cost of care (“Proactive Prediction”)

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Committee Accomplishments and Deliverables

- Vignettes completed
  - Short, concrete “day-in-the-life” use cases that demonstrate proactive prediction workflows
  - Emphasis on realistic data inputs, operational touchpoints, and clinical actionability
- White paper submitted
  - Defines the architectural/strategic framework for transformation
  - Positions AI as an enabling layer, not a standalone project
- Critical AI opportunity map
  - Identifies the highest-leverage, lowest-barrier areas where labs can act first and act safely

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"From Result to Intervention": The CL 2.0 Informatics/AI Operating Model

- Data foundation (what the lab already has)
  - LIS data + historical results + metadata (location, service, timing, specimen, analyzer flags)
  - Minimal additional inputs: demographics, encounter type, problem list (when available)
- Analytics layer (what AI contributes)
  - Trend detection, state estimation, forecasting, risk stratification, uncertainty estimates
- Action layer (what makes it CL 2.0)
  - Closed-loop workflows: alert → confirm → route → intervene → document → measure outcomes
  - "Right signal, right person, right time" with governance and auditability

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The Top 10 Practical AI/Predictive Modeling Opportunities for Proactive Prediction

1. AKI and CKD progression forecasting
2. Deterioration early warning from routine labs (readmission bounce-back / sepsis / ICU transfer risk)
3. Electrolyte/acid-base instability prediction (ED bounce-back, arrhythmia risk proxy)
4. Silent anemia/bleeding risk detection and trajectory prediction
5. Medication-related efficacy and hazard prediction (ineffectiveness / toxicity)

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The Top 10 Practical AI/Predictive Modeling Opportunities for Proactive Prediction

6. Lab utilization optimization that improves outcomes and not just cost
7. Preanalytic and analytic quality prediction (error prevention upstream)
8. Microbiology: earlier escalation / de-escalation signals
9. Population risk stratification from lab-only and lab-clinical chart data
10. Operational forecasting that enables clinical impact

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Implementation Path That Avoids "Insurmountable Barriers"

- Start with "low lift, high trust"
  - Use data the lab already controls (LIS + analyzer metadata)
    - Choose 1–2 vignettes that are measurable and workflow-compatible
- Deploy as decision support, not autonomy
  - Risk score + explanation + recommended action; clinician remains decision-maker
- Governance and safety
  - Clear thresholds, monitoring for false positives, bias checks, drift detection
  - Audit trails, human-in-the-loop escalation pathways
- Measurement
  - Clinical outcomes (avoidance of deterioration events), cost outcomes (reduced high-cost episodes), process metrics (turnaround, redraws, alert burden)
- Scale
  - Expand from one disease pathway to a portfolio; standardize the build pattern

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Upcoming Thematic Thrusts for the Committee

- Serve as an implementation science resource for the collective Clinical Lab 2.0 committees, working in close partnership with the Demonstration Committee, to prioritize efforts.
- Continue building pilot tools that demonstrate the “Art of the Possible” in terms of the value proposition of lab data to transform healthcare into reproducible models of *Proactive Prediction*
- Generate candidate open-source service models that can be exported to interested parties.