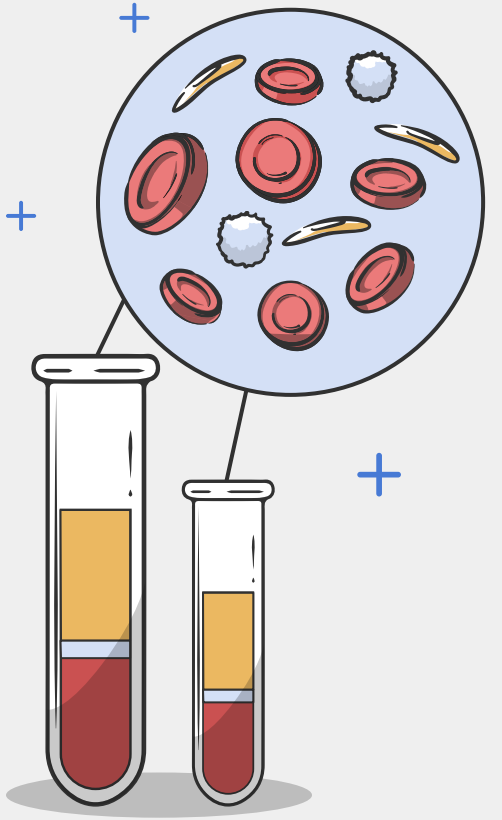
Insight Into AI-Based Lab Tools

Vitality Robotics



Paul McLean, Tim Cao, Nia Sayyed, Sam Mellott, Lola Olosu

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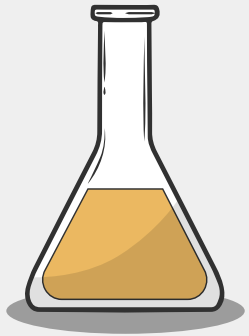

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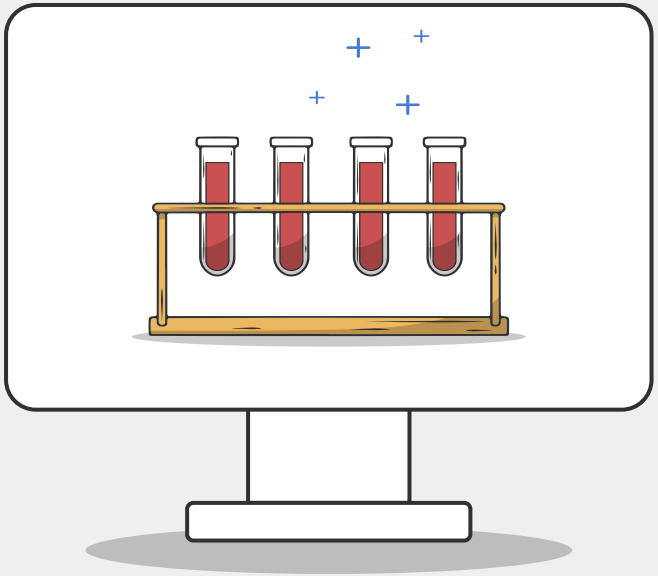

01

Labtools.AI & Vitality Robotics

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What is Vitality Robotics?

LABTOOLS.AI

Founder - Dr. Joe Webb

Designs AI-powered hardware + software to automate scientific or veterinary workflows.

Vitality Robotics: Automates preclinical surgical tasks such as tissue collections, injections and necropsies.

Labtools.AI: Software focus, creates automated tools for analytical instruments, inventory management, electronic lab notebooks (ELN), etc.

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Automating Scientific Workflows

Save Time

Lab procedures can be time-consuming and tedious

Streamline Analyses

Automation/AI increases productivity and reproducibility in the lab

Reduce Costs

Time is money! Labs are often limited by funding

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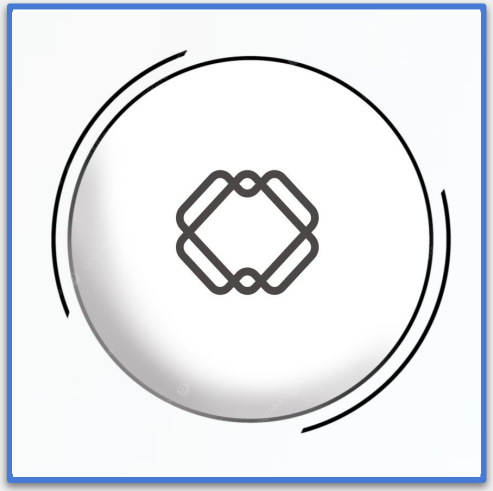
LabTrackerz™ (Inventory)

Tap-it-to-track-it™ System

- MLMs (Machine Learning Models) are custom trained on your inventory usage patterns
  - Real time inventory tracking synced with instrument runs
  - Prevents stockouts
  - Forecasts reorder dates



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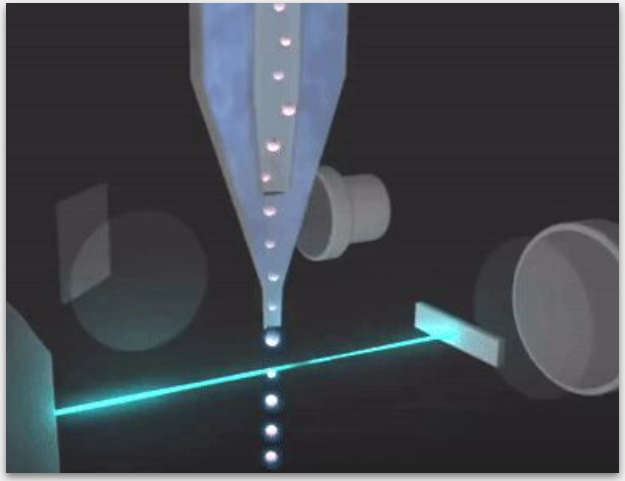
LabInCytes™ (IBFC)

What is it?

- **Image Flow Cytometry (IFBC)** combines traditional flow cytometry + high-resolution imaging
- Think of a flow cytometer + Brightfield microscopy at the same time.
- Measure fluorescence intensity, size, morphology, biomarkers, etc.



As each cell passes the laser, the machine measures **size, complexity**, and **fluorescence** (if the cell is labeled with fluorescent markers. It also takes images at the same time.

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LabIncytes
A Novel IFBC Tool

Upload Files → **Generate Data** → **Visualize Results**

Digital Fluorescence

Generates synthetic fluorescence for 10-1000 biomarkers with data from any IBFC instrument without additional hardware

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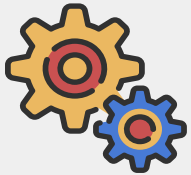
Problems with IBFC

Expensive

Excluding labor, supplies cost **$30/sample + $32/hour labor cost** (~6 samples per hour with 1 hour run time minimum)

Hours of Labor

Sampling is tedious - requiring **~6 hours of sample preparation** (labeling)



Capacity

Additional lasers ($15k-90k) are required to measure >2 biomarkers simultaneously, with a **max of 15 per sample**

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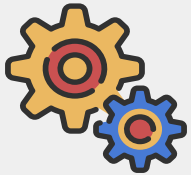
Solution: LabIncytes

Affordable

LabInCytes eliminates expensive labeling steps, reducing per-sample costs to as low as $10 with high-volume usage.

Low Maintenance

Real-time, label-free imaging removes the need for ~6 hours of sample preparation.



Broad Spectrum

Analyze up to 1000 proteins per sample without costly hardware expansions like extra lasers.

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Problem & Significance

Labtools.AI offers tools to expedite IBFC analysis and improve inventory management, but currently lacks the manpower and deep industry insight needed to fully capitalize on these opportunities.

This project will help the company better understand customer needs and refine its value propositions based on direct survey feedback.

Our Goals

1. **Create LabTrackerz Report/Whitepaper (Via Primary Market Research + Surveys)**
2. **Creation of Marketing Collateral for LabInCytes and LabTrackerz**
3. **Competitive Landscape for Digital IBFC and Inventory/Device Management Tools**
4. **Regulatory Analysis of AI + IBFC + Medical Devices**

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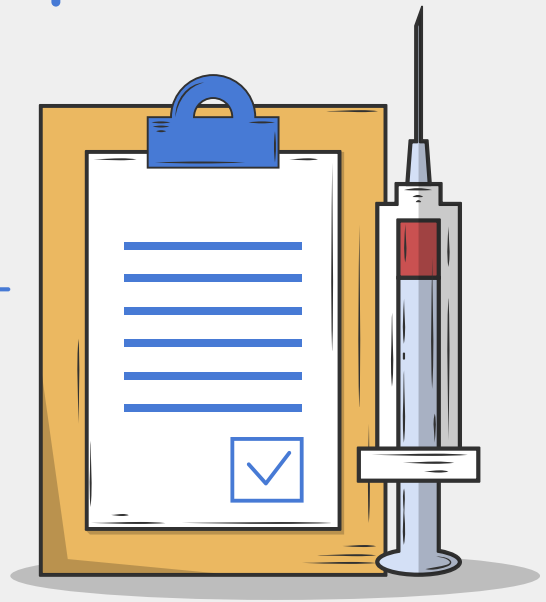
02

Deliverables

Whitepaper & Individual Deliverables



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Deliverable #1

IBFC Outreach & Feedback

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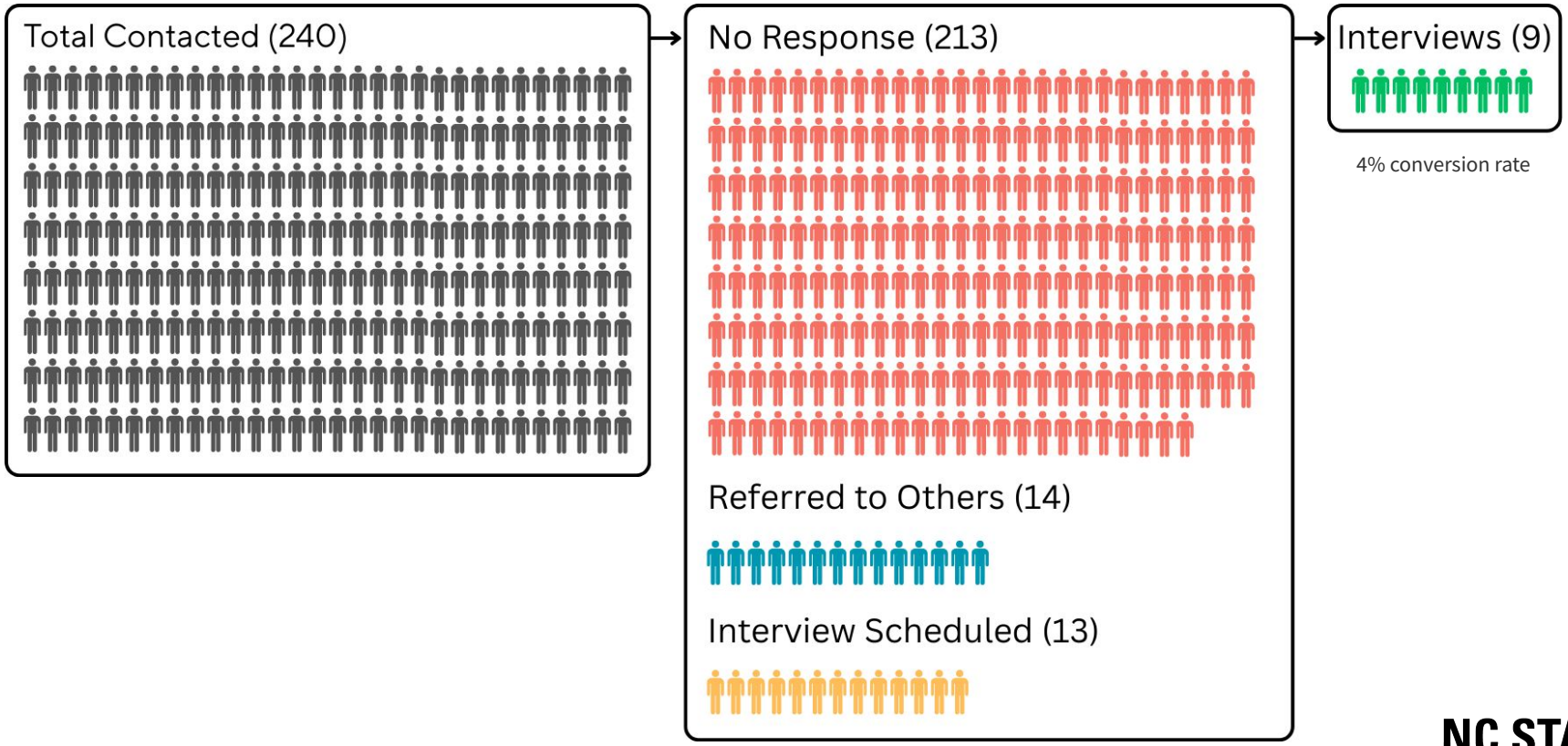
Image Based Flow Cytometry Outreach



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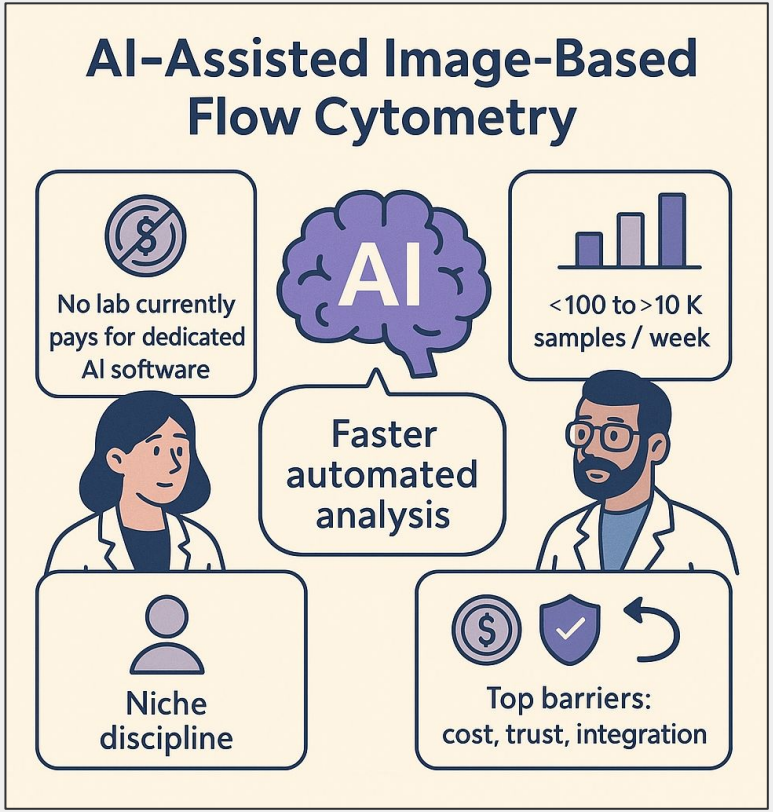
Survey Analysis

- **Automated Analysis**
  - Cuts down on gating time
- **Niche Field**
  - Many Flow Cytometry Cores lack instrumentation
- **Variation in IBFC Sample Processing**
- **Biggest Adoption Hurdles**
  - Cost Justification
  - Trust in Accuracy
  - Ease of Lab Integration



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Deliverable #2

Marketing Collateral

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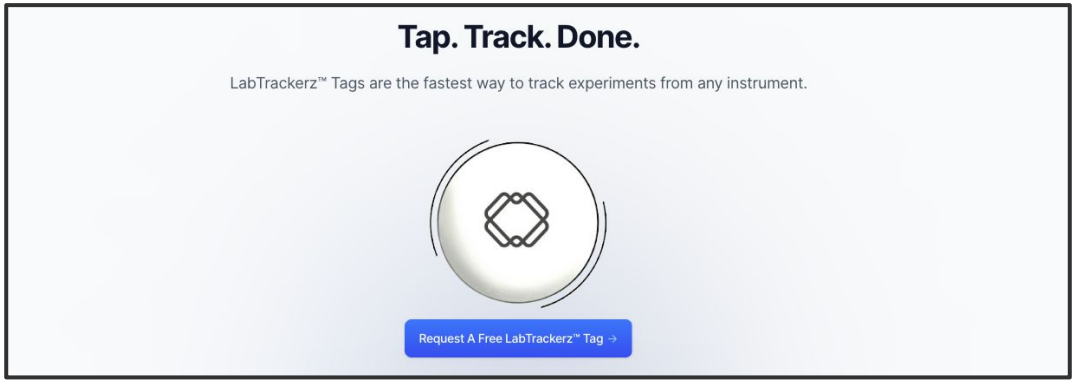
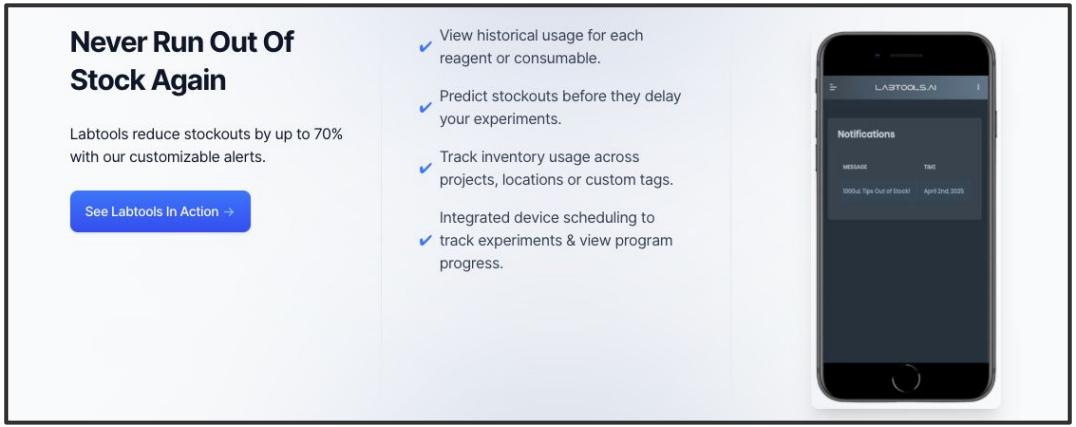
Advertisements

https://www.labtools.ai/





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Deliverable #3

Competitive Analysis

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Competitive Analysis - LabTrackerz

Features	LabTrackerz	LabGuru	Quartzy	Scinote
Inventory Management	Automatic	Manual	Manual	Manual
Cloud Based Access	✓	✓	✓	✓
Reporting & Exporting	✓	✓	Limited	Limited
Scalability/Flexibility	✓	✓	Limited	Limited
Audit Trails & Compliance Tracking	✓	Limited		
Transparent Pricing	✓	✓		
Vendor Neutral	✓			
Automated Forecast Stockouts	✓			
Integrable with Labtools.AI	☆	✓	✓	✓

Why LabTrackerz?

✅ Instant Tap-to-Track updates

✅ Smart reordering with AI-powered demand forecasting

✅ Affordable plans for any lab size

✅ Vendor-neutral — works with all your suppliers

✅ Scales from small research teams to global enterprises

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Competitive Analysis - IBFC

Features	IBFC	AMNIS IMAGESTREAM	BD FACSYPROW	THERMO-FISHER
Multiplex Protein Detection	>1000 proteins	<15	<15	<15
Real-Time Quantification	✓	✗	✗	✗
Brightfield + Label-Free Imaging	✓	✗	✗	✗
Cloud-Based Data Management	✓	Low	Limited	Limited
AI-Driven Analysis	✓	Limited	Restricted	Restricted
Throughput per Minute	>100 samples/min	~15 samples/min	<5 samples/min	<5 samples/min
Flexible Pricing	✓	✗	✗	✗
Vendor-Neutral Integrations	✓	✗	✗	✓
Compatitbility	☆	✓	✓	✓

Amnis ImageStream

"Powerful images. But low flexibility."

High-resolution cell images

❌Limited multiplexing (<15 proteins)

❌Requires fluorescent labeling

❌Slower analysis pipeline

➡️LabInCytes enables high-throughput, label-free imaging — ideal for discovery labs.

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Deliverable #4

Regulatory Analysis

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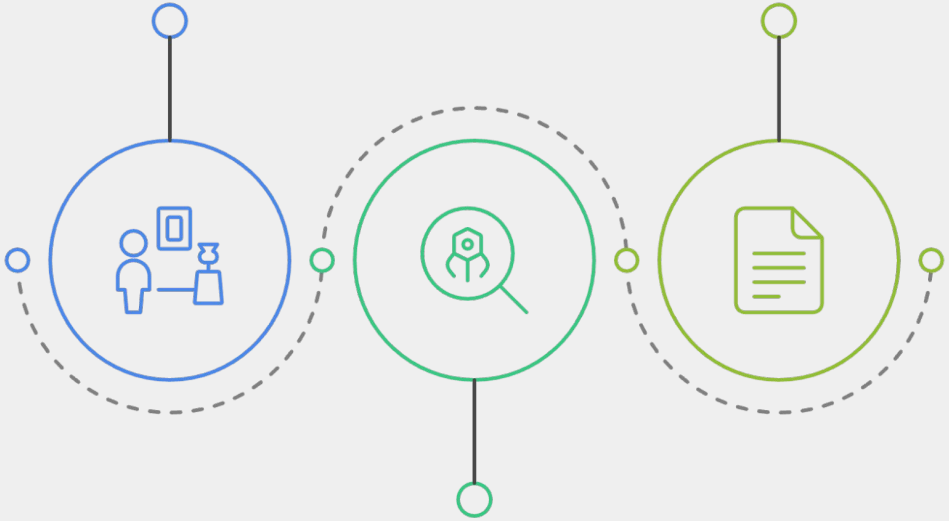
Meet with Joe

Initial meeting to understand company verticals

Generate Master Document

Compilation of findings into a comprehensive document



Investigate Regulatory Landscape

Independent research on regulatory environment

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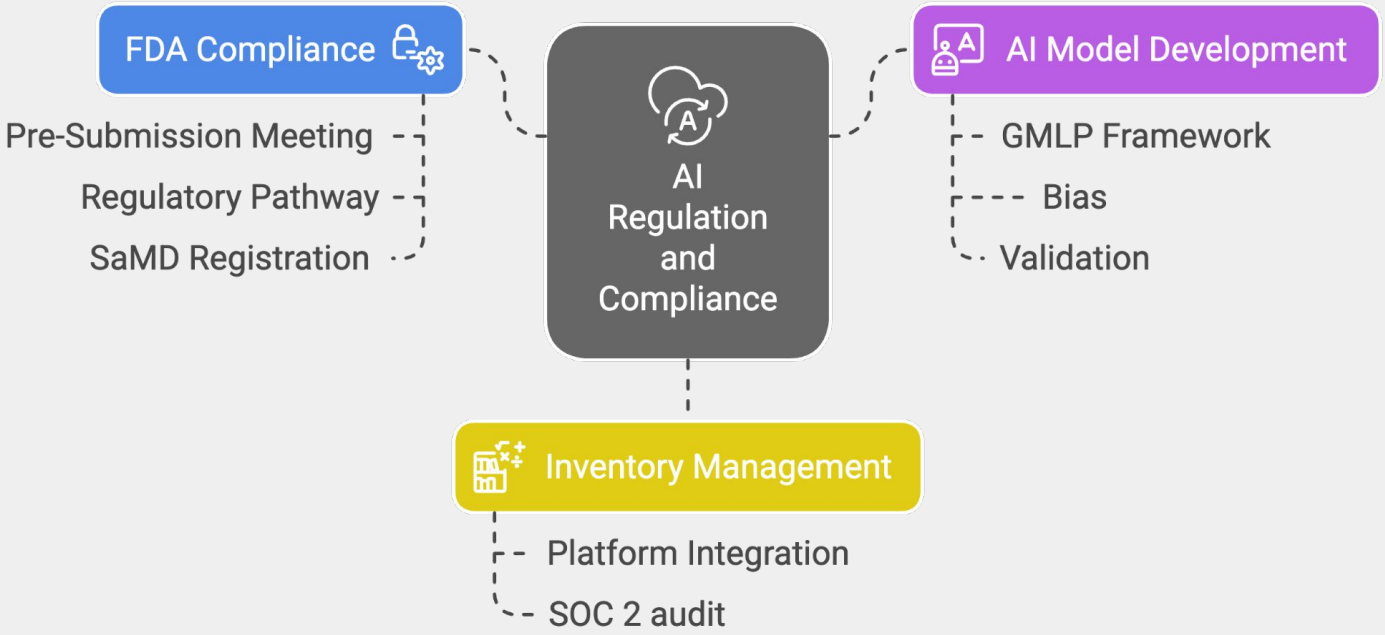
Regulatory Analysis



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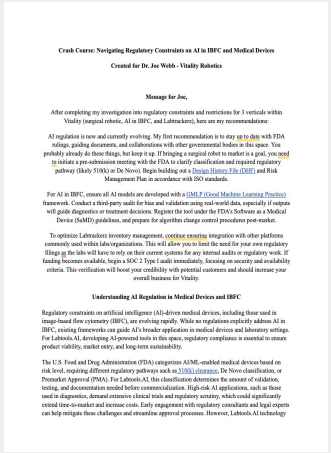


Crash Course: Navigating Regulatory Constraints on AI in IBFC and Medical Devices

Created for Dr. Joe Webb - Vitality Robotics

Message for Joe,

After completing my investigation into regulatory constraints and restrictions for 3 verticals within Vitality (surgical robotic, AI in IBFC, and Labtrackers), here are my recommendations:

AI regulation is now and currently evolving. My first recommendation is to stay up to date with FDA rulings, guiding documents, and collaborations with other governmental bodies in this space. You probably already do those things, but keep it up. If bringing a surgical robot to market is a goal, you need to initiate a pre-submission meeting with the FDA to clarify classification and required regulatory pathway (likely 510(k) or De Novo). Begin building out a Design History File (DHF) and Risk Management Plan in accordance with ISO standards.

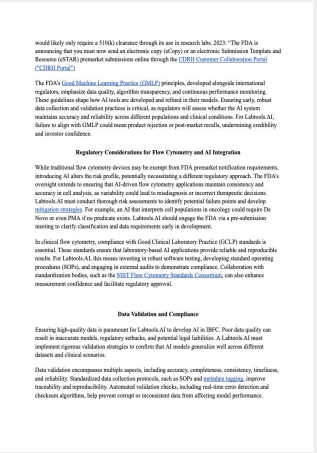
For AI in IBFC, ensure all AI models are developed with a GMLP (Good Machine Learning Practice) framework. Conduct a third-party audit for bias and validation using real-world data, especially if outputs will guide diagnostics or treatment decisions. Register the tool under the FDA's Software as a Medical Device (SaMD) guidelines, and prepare for algorithm change control procedures post-market.

To optimize Labtrackerz inventory management, continue ensuring integration with other platforms commonly used within labs/organizations. This will allow you to limit the need for your own regulatory filings as the labs will have to rely on their current systems for any internal audits or regulatory work. If funding becomes available, begin a SOC 2 Type I audit immediately, focusing on security and availability criteria. This verification will boost your credibility with potential customers and should increase your overall business for Vitality.

Understanding AI Regulation in Medical Devices and IBFC

Regulatory constraints on artificial intelligence (AI)-driven medical devices, including those used in image-based flow cytometry (IBFC), are evolving rapidly. While no regulations explicitly address AI in IBFC, existing frameworks can guide AI's broader application in medical devices and laboratory settings. For Labtools.AI, developing AI-powered tools in this space, regulatory compliance is essential to ensure product viability, market entry, and long-term sustainability.

The U.S. Food and Drug Administration (FDA) categorizes AI/ML-enabled medical devices based on risk level, requiring different regulatory pathways such as 510(k) clearance, De Novo classification, or Premarket Approval (PMA). For Labtools.AI, this classification determines the amount of validation, testing, and documentation needed before commercialization. High-risk AI applications, such as those used in diagnostics, demand extensive clinical trials and regulatory scrutiny, which could significantly extend time-to-market and increase costs. Early engagement with regulatory consultants and legal experts can help mitigate these challenges and streamline approval processes. However, Labtools.AI technology



would likely only require a 510(k) clearance through its use in research labs. 2023: "The FDA is announcing that you must now send an electronic copy (eCopy) or an electronic Submission Template and Resource (eSTAR) premarket submissions online through the CDRH Customer Collaboration Portal ("CDRH PortalÓ)

The FDA's Good Machine Learning Practice (GMLP) principles, developed alongside international regulators, emphasize data quality, algorithm transparency, and continuous performance monitoring. These guidelines shape how AI tools are developed and refined in their models. Ensuring early, robust data collection and validation practices is critical, as regulators will assess whether the AI system maintains accuracy and reliability across different populations and clinical conditions. For Labtools.AI, failure to align with GMLP could mean product rejection or post-market recalls, undermining credibility and investor confidence.

Regulatory Considerations for Flow Cytometry and AI Integration

While traditional flow cytometry devices may be exempt from FDA premarket notification requirements, introducing AI alters the risk profile, potentially necessitating a different regulatory approach. The FDA's oversight extends to ensuring that AI-driven flow cytometry applications maintain consistency and accuracy in cell analysis, as variability could lead to misdiagnosis or incorrect therapeutic decisions. Labtools.AI must conduct thorough risk assessments to identify potential failure points and develop mitigation strategies. For example, an AI that interprets cell populations in oncology could require De Novo or even PMA if no predicate exists. Labtools.AI should engage the FDA via a pre-submission meeting to clarify classification and data requirements early in development.

In clinical flow cytometry, compliance with Good Clinical Laboratory Practice (GCLP) standards is essential. These standards ensure that laboratory-based AI applications provide reliable and reproducible results. For Labtools.AI, this means investing in robust software testing, developing standard operating procedures (SOPs), and engaging in external audits to demonstrate compliance. Collaboration with standardization bodies, such as the NIST Flow Cytometry Standards Consortium, can also enhance measurement confidence and facilitate regulatory approval.

Data Validation and Compliance

Ensuring high-quality data is paramount for Labtools.AI to develop AI in IBFC. Poor data quality can result in inaccurate models, regulatory setbacks, and potential legal liabilities. A Labtools.AI must implement rigorous validation strategies to confirm that AI models generalize well across different datasets and clinical scenarios.

Data validation encompasses multiple aspects, including accuracy, completeness, consistency, timeliness, and reliability. Standardized data collection protocols, such as SOPs and metadata tagging, improve traceability and reproducibility. Automated validation checks, including real-time error detection and checksum algorithms, help prevent corrupt or inconsistent data from affecting model performance.

However, automation alone is insufficient. Human oversight, through data stewards or domain experts, is necessary to review critical datasets and identify edge cases where AI may struggle.

Utilizing third-party datasets and engaging in peer-review processes ensures that AI models are not biased toward specific sample populations. Ethical considerations are also critical, as biased data can lead to disparities in healthcare outcomes. Adhering to frameworks like the Data Equity Framework (We All Count) can help mitigate unintended biases and promote fair AI applications.

Regulatory Compliance and Data Governance Strategies

Beyond technical validation, Labtools.AI must align its operations with regulatory compliance requirements. The FAIR Data Principles: Findable, Accessible, Interoperable, and Reusable provide a foundation for structuring and managing research data. Implementing version control mechanisms, such as Git or Data Version Control (DVC), ensures that all data modifications are tracked and reproducible. Provenance tracking further strengthens transparency by documenting how data is collected, processed, and used in AI model development.

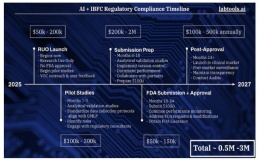
In healthcare and life sciences, regulatory frameworks like GDPR (for data privacy in Europe) and HIPAA (for patient data protection in the U.S.) impose strict guidelines on data handling. Labtools.AI must establish robust data security measures, including encryption and access control, to comply with these regulations. Failure to do so can result in severe legal and financial consequences, including fines and loss of stakeholder trust. Compliance with Good Machine Learning Practice (GMLP) principles, as advocated by regulatory bodies, is also crucial to demonstrating transparency, accountability, and long-term AI performance monitoring.

Challenges and Opportunities

Labtools.AI in the IBFC space faces significant regulatory challenges, but these also present opportunities. Regulatory compliance may seem like a barrier, but successfully navigating these requirements can provide a competitive edge by demonstrating reliability and safety to investors, partners, and customers. Engaging with regulatory bodies early in the development process (during pilot studies is recommended), leveraging standardization efforts, and investing in rigorous data validation can facilitate smoother approval processes and reduce long-term risks.

Emerging regulatory trends, such as the FDA's Total Product Lifecycle (TPLC) approach, indicate a shift toward more adaptive AI oversight. This approach allows AI models to evolve while maintaining safety and effectiveness, opening the door for Labtools.AI to implement continuous learning mechanisms in their AI solutions. Additionally, the Predetermined Change Control Plan (PCCP) offers a structured pathway for FDA-approved AI modifications without requiring a full re-approval process, reducing regulatory burdens for iterative AI improvements.

Timeline



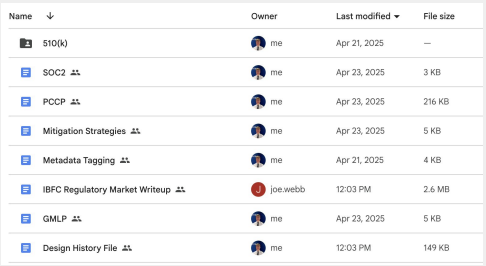
Other Cost Considerations

Navigating regulatory pathways requires careful financial planning. Costs associated with regulatory compliance include:

- Pre-market approval and testing: $50,000–$500,000 depending on device classification.
- Clinical trials for high-risk devices: $1 million–$5 million. Needed for Labtools.AI?
- Legal and regulatory consultancy fees: $10,000–$100,000 annually.
- Data validation and compliance software: $5,000–$50,000 annually.
- Security and data governance implementation: $20,000–$200,000.

Full Regulatory Approval

- Regulatory consulting & legal fees: ~$100K+
- Analytical & clinical validation studies: $500K - $2M
- FDA submission & review fees: ~$20K (510(k) small business discount, higher for De Novo)
- Total estimated cost: $1M - $3M



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510(k)	me	Apr 21, 2025	–
SOC2	me	Apr 23, 2025	3 KB
PCCP	me	Apr 23, 2025	216 KB
Mitigation Strategies	me	Apr 23, 2025	5 KB
Metadata Tagging	me	Apr 21, 2025	4 KB
IBFC Regulatory Market Writeup	joe.webb	12:03 PM	2.6 MB
GMLP	me	Apr 23, 2025	5 KB
Design History File	me	12:03 PM	149 KB

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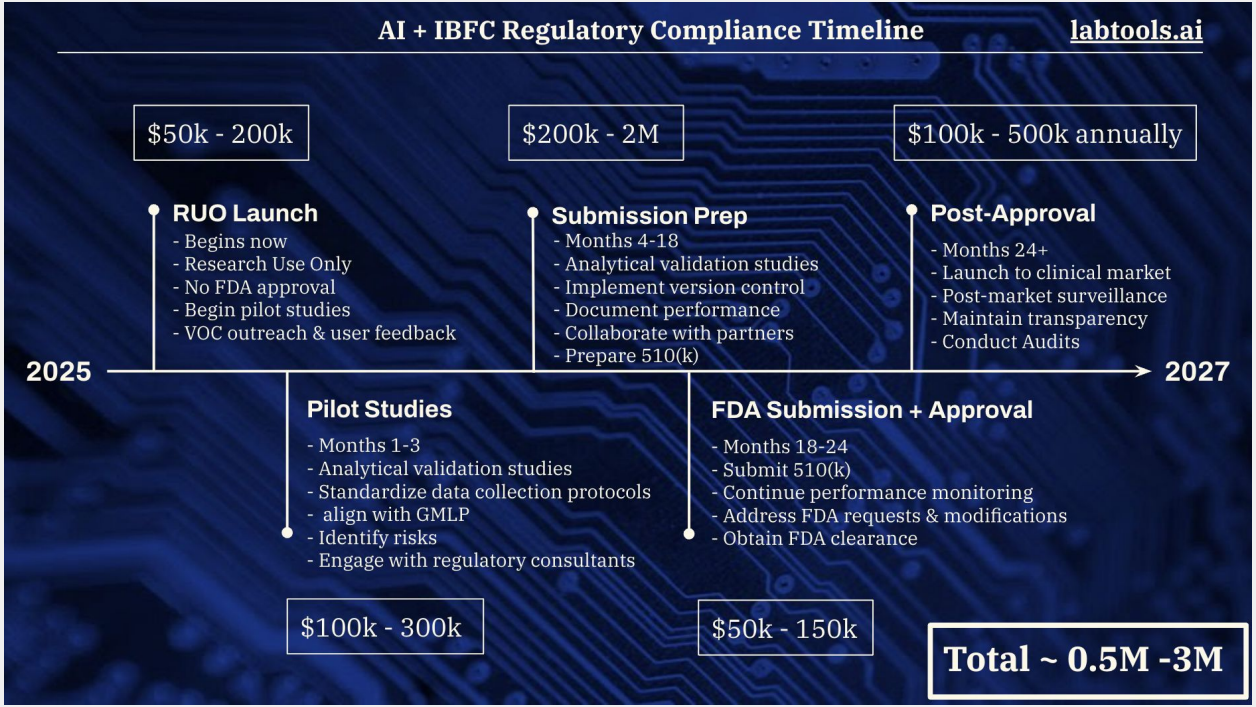
Potential Timeline



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Deliverable #5

LabTrackerz Survey & Whitepaper

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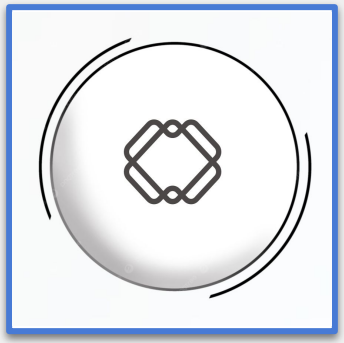
The Pivot

- **IBFC is very niche**
- Joe informed us that LabTrackerz has already had gained traction and interest with companies he met with in industry

As a result, we collectively we decide to pivot into focusing on LabTrackerz.



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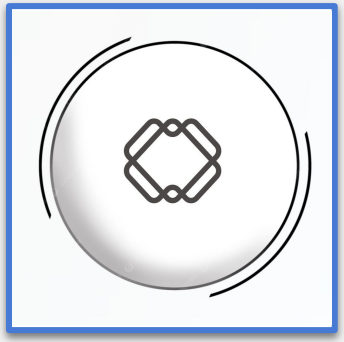
Goals

To find out:

1. What tools are people using now for inventory tracking?
2. What tools do people want to use make inventory tracking easier?

Is LabTrackerz and the features it offers something people would want?



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LabTrackerz Outreach

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Demographics

51%

of respondents represented scientific & analytical staff, an additional 22% represented process development (Engineers, MSAT, etc.)

49%

of the professionals surveyed had **≥7** years of experience, with an average of **8** years

60%

of respondents identified themselves as responsible for placing inventory orders

22%

of respondents held leadership roles (director, manager, supervisor, etc.)

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Example of Questions Asked

- What system does your lab use to track inventory?
- Who is responsible for placing re-orders in your lab?
- How often do inventory-related issues (e.g., stockouts, expired reagents, misplaced items) impact your lab’s efficiency?
- What features would be most valuable for you? (Please rank in order of importance)
- How much do you think your lab would benefit from an inventory management system that minimizes or eliminates manual input (e.g., automated tracking, reordering, and auditing)?
- How valuable would automated reordering (triggered by low stock or expiration) be for your lab's inventory management?

Whitepaper

2025 Report

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Challenges with LabInCytes

1. IBFC Response rates were low

   Why? IBFC is very new and niche - first model made in 2000s, more made in the 2010s.

   i. Modern lab instruments - standard flow cytometry, liquid chromatography came out in the 60s/70s. Microscopy: 400+ years old.

   We exhausted all academic options across the country - surprisingly large institutions don't have IBFC (Harvard, Stanford, U Michigan, etc.)

   i. These are high volume facilities that surprisingly do not carry this instrument

   ii. Not a lot of users in academic spaces on this instrument, unlikely to meet volume of >100 sample/week.

      1. Why would a user need to use both flow + microscope simultaneously?

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Challenges Continued

2. Time Constraints
    a. We have spent around 1 month doing outreach, competitive analysis, and marketing collateral creation
    b. Unsure of what non-academic spaces use this instrument
    c. May need to search out of the USA
        i. Cytek (main manufacturer on IBFC instrument) reported high sales in Europe and Asia Pacific

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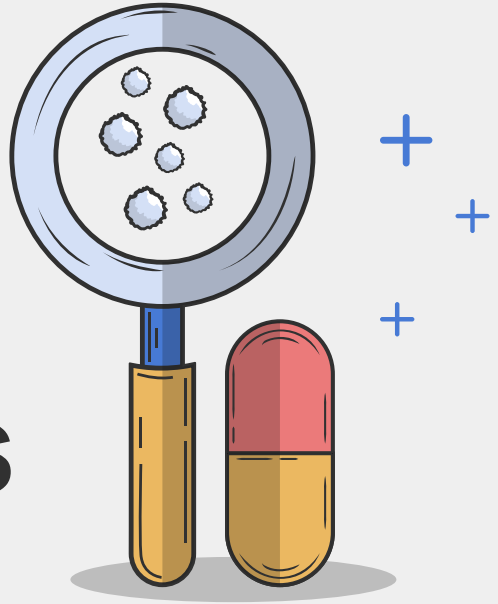
03

Recommendations



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Strategic Recommendations

Shift To Labtrackerz

- Target high volume labs
- Biopharma
- Consumer healthcare

Engage With Regulatory Partners Early

- Document often!
- SOC 2 verification
- Follow GMLP

Emphasize Ease Of Use + Automation

- Some professionals are wary of AI…

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Thank You, Mentors

Dr. Joe Webb

Meaghan Nappo

Dr. Sue Carson

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Thanks!

Do you have any questions?

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