

**Executive War College**

May 1, 2019



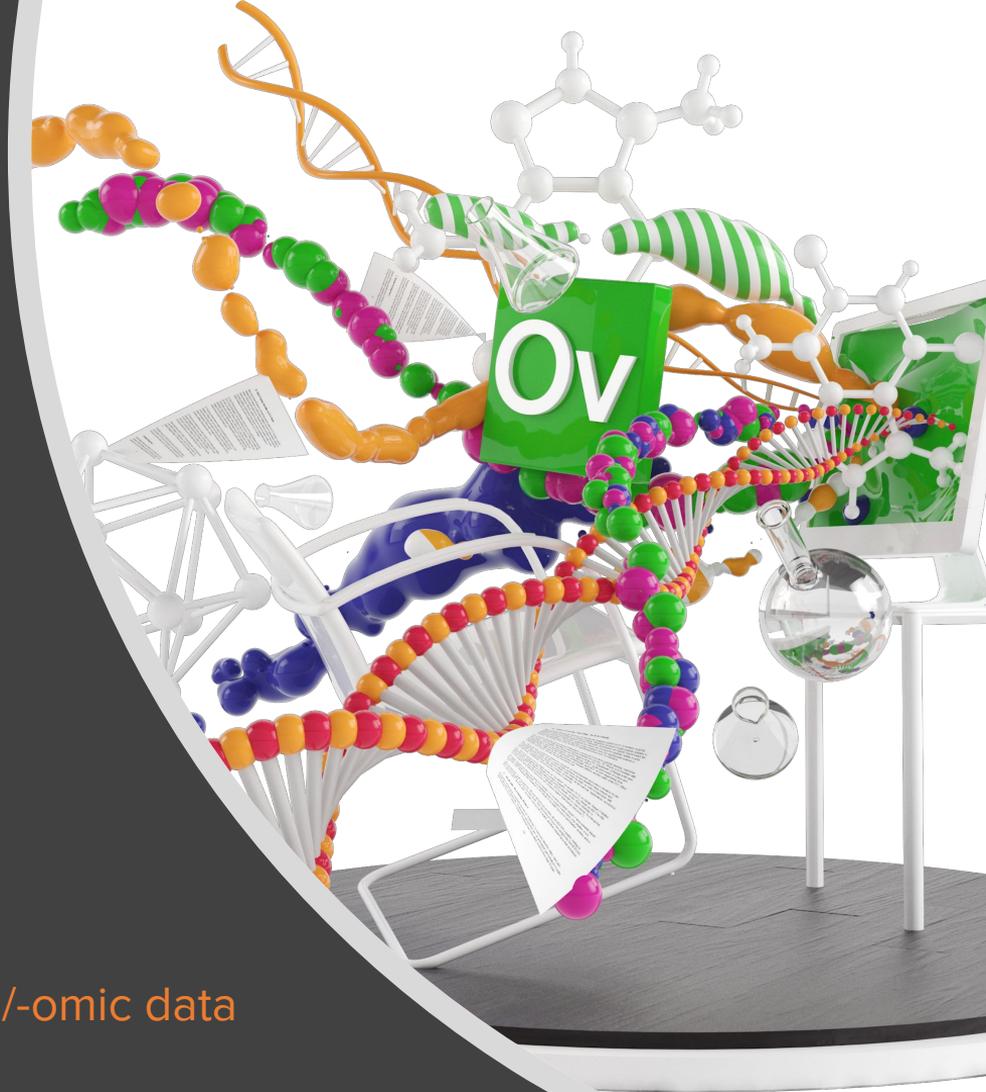
**Positioning Your Lab to be the  
Keystone for Precision Medicine  
in Your Community**

Barry Wark, PhD  
Co-Founder/CEO

# Today

- My background
- What is modern (next-generation) informatics?
- Why should you consider adopting a modern informatics stack?
- Case study: Volente Diagnostics
- Vision of the future
- Action Plan

Unlock the opportunity for clinico/-omic data



# My Background



- I've been a software engineer for decades. The first software I wrote was a validated analysis tool for the Molecular Diagnostics Lab at University of Minnesota
- BS in Symbolic Systems at Stanford (Computer Science and A.I.)
- Ph.D. in Neurobiology and Behavior at Univ. of Washington (Neurophysiology)
- Physion Consulting, INCF
- Ovation

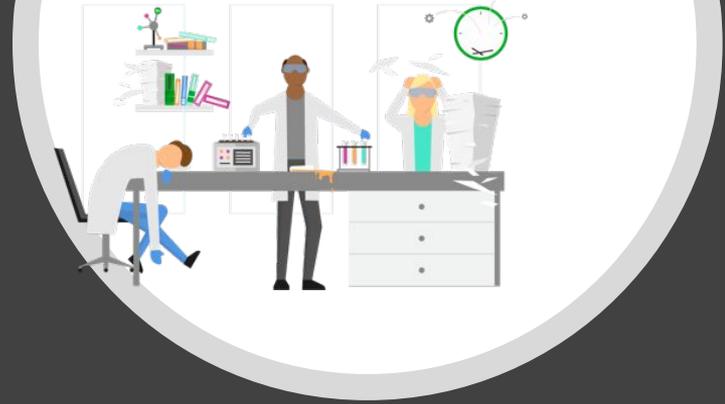
# Lab Informatics Challenges

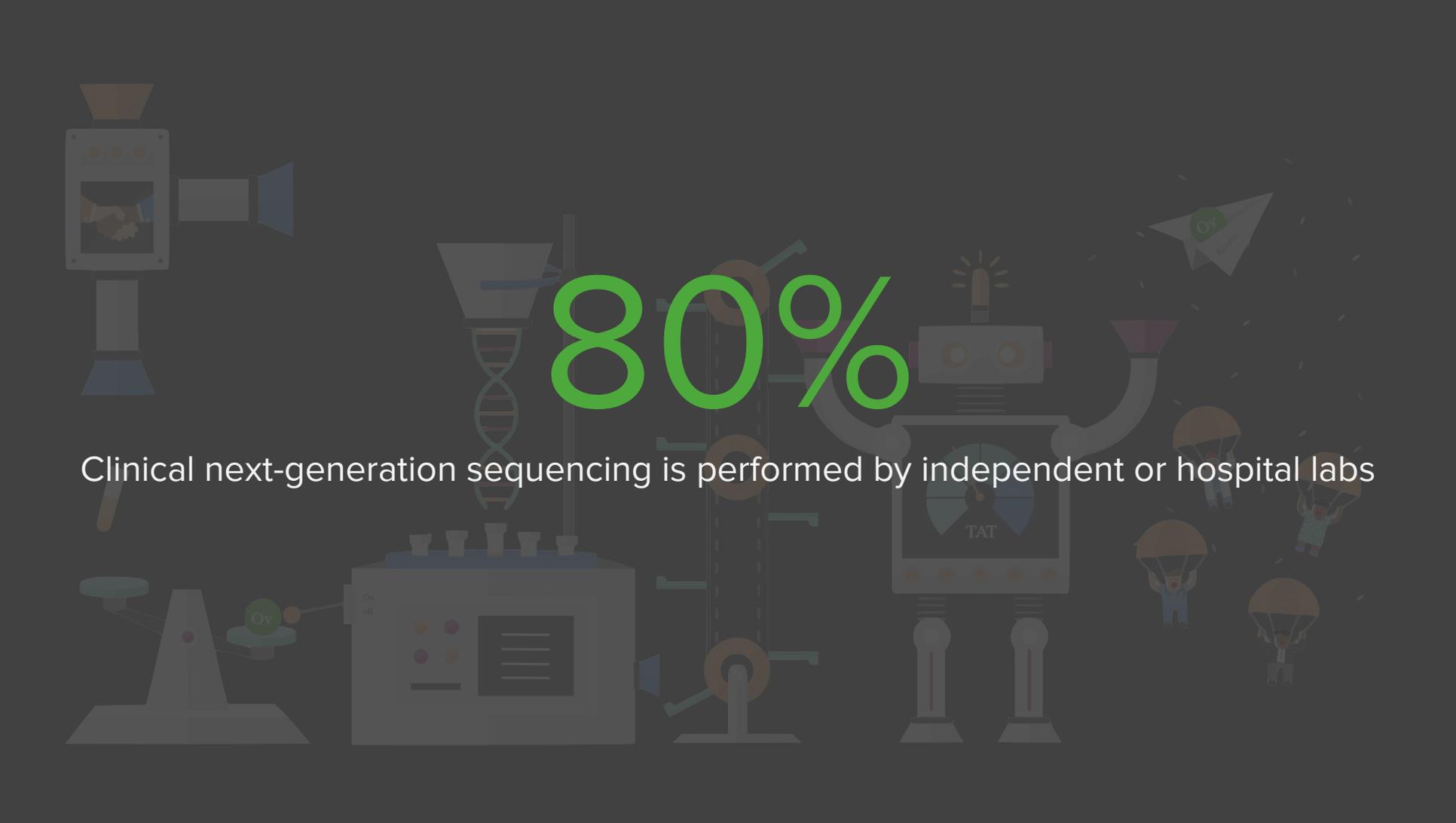
- Operations

- Information handoff between services (CRM, EHR, RCM, interpretation, etc.)
- Multi-site, collaborative Dx
- X-omic big data
- New applications/workflows/technologies, proprietary diagnostics

- Community

- Real World Evidence
- Outcomes-based reimbursement
- Seizing this new opportunity:
  - Consent
  - Data model
  - Informatics





80%

Clinical next-generation sequencing is performed by independent or hospital labs



What is modern (Next-generation) informatics?

- Delivery
- Architecture
- Design

# Next-generation Informatics: Delivery

- “Software as a Service” (SaaS)
- Cloud-based
- Web-browser client application

## Benefits for the lab...

How we deploy and consume software applications has changed...

- Lower Total Cost of Ownership
- Focuses on your core expertise
- Capital vs. Operating benefits

# Next-generation Informatics: Architecture

- Expertise
- Redundancy
- Availability
- **Security**
  - HIPAA
  - SOC2
  - GDPR

## Benefits for the lab...

How we architect software infrastructure has changed...

- High-availability
- Scalability (burst capacity)
- Instant multi-site deployments
- Cross-organization access (when desired)
- *Best-in-class* security



# Next-generation Informatics: Architecture

## Zero-trust security

- Pioneered by cloud providers (Google)
  - Used by many of the largest technology companies
  - Fully HIPAA/SOC2 compliant
- Authentication/authorization at every interaction, not just at the boundary
- Not relying on VPNs or firewalls

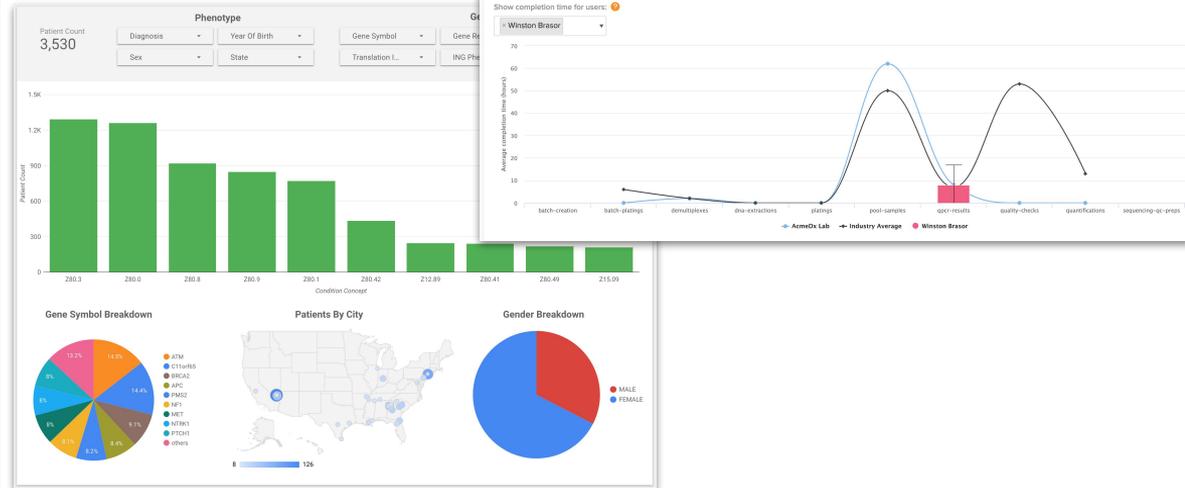
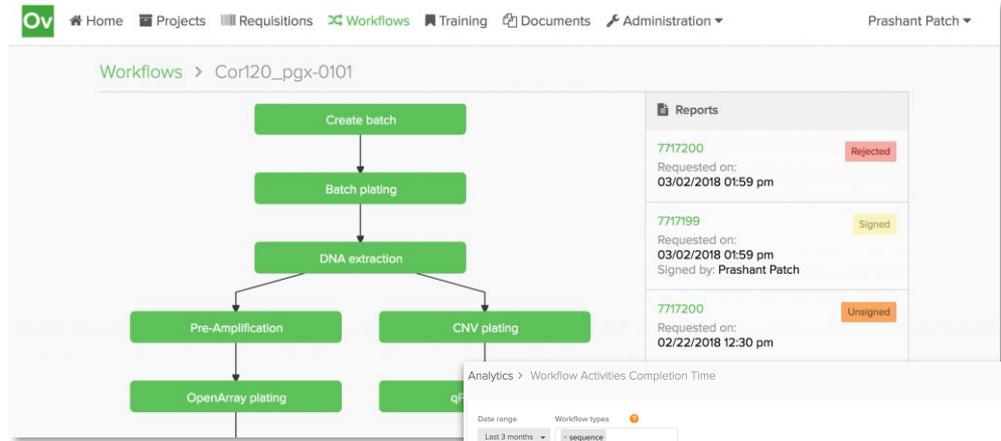
## Benefits for the lab...

How we secure software applications and infrastructure has changed...

- Fine-grained authorization
- Secure application access from any modern browser (even mobile)
- Security “from the ground-up” so you don’t have to retrofit or re-develop after each informatics change
- Liberating, agile evolution of your informatics stack

# Next-generation Informatics: Design

- Software
  - Modular service architecture
  - Automated test coverage
- Human-centered design



# un·LIM·it·ed

/,ən'limidəd/

*adjective*

1. not restricted

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- LIS + LIMS + ...
- Best-in-class partners
- Big data
- Multi-site deployments
- Proprietary diagnostics
- Useable, actionable data
  - Operational analytics
  - Value-add aggregate data for customers



# Case Study

Volente Diagnostics



V O L E N T E | D X

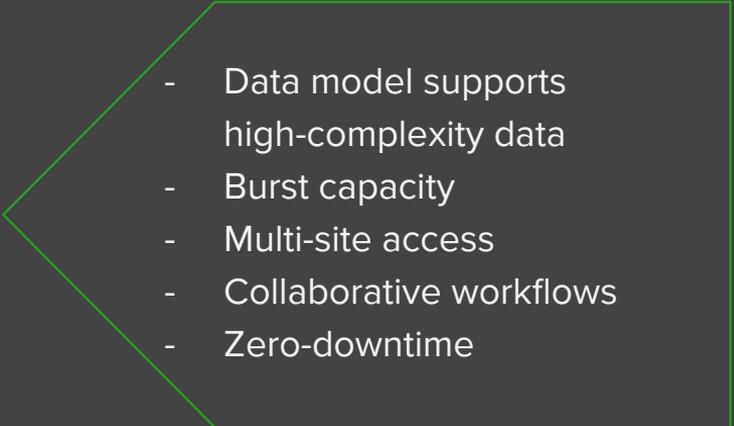
# Mission & challenges

## Status quo molecular infectious disease

- Limited menu
- Providers struggle to derive actionable insight

## Challenges

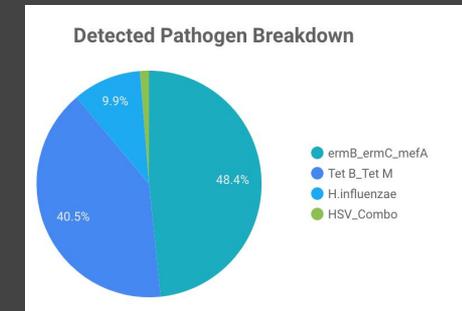
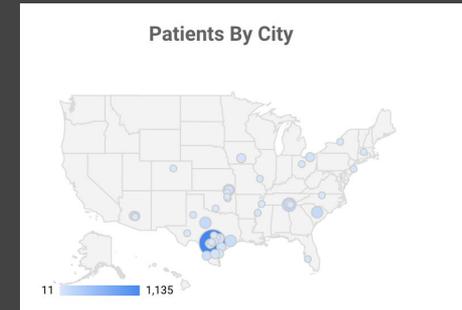
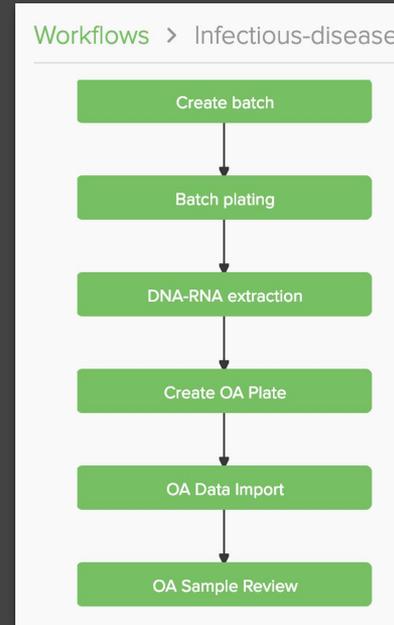
- Large menu (15+ panels, 180+ tests)
- Big data
- Collaboration with PharmD
- Rapid turn-around
- Multi-site expansion

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- Data model supports high-complexity data
  - Burst capacity
  - Multi-site access
  - Collaborative workflows
  - Zero-downtime

“Nobody had done what we’ve done. It was a custom operation from the beginning”

# Solution — Ovation Diagnostic

- Roll-out...on schedule.
- Proprietary interpretation & report
- Integrations: Xifin, CRM, PharmD
- Ready for rapid growth



“Ovation has always been there for us throughout this process.”

# Volente Keys to Growth

## Confidence in technology partner

- Incubate new molecular workflows in Ovation

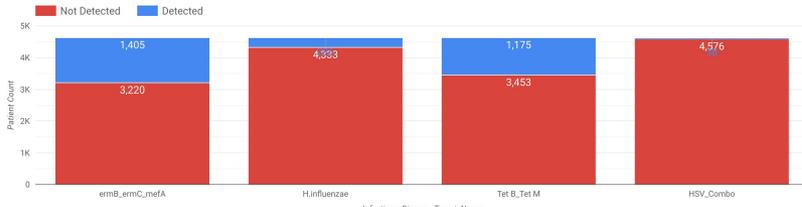
## Data Services

- Feedback through dashboards
- Business analytics
- Value-add: localized epidemic identification and tracking

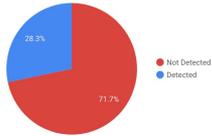
## Scale-out

- 5 year plan: world-wide lab network
- Consistent, turn-key informatics stack

“We found the right partner and we never considered turning back”



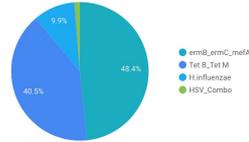
Results Breakdown



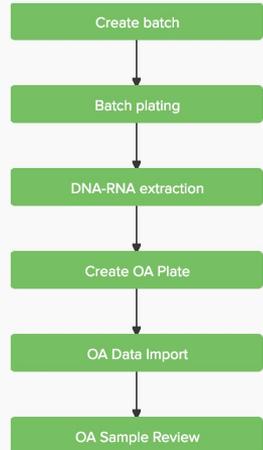
Patients By City



Detected Pathogen Breakdown



Workflows > Infectious-disease



# Outcomes

Modern informatics unlocks opportunity.

- Ready to launch
- Ready for growth: lab, network
- Network-wide data services
  - Internal analytics
  - Proprietary diagnostic R&D
  - Provider reports (value-add)

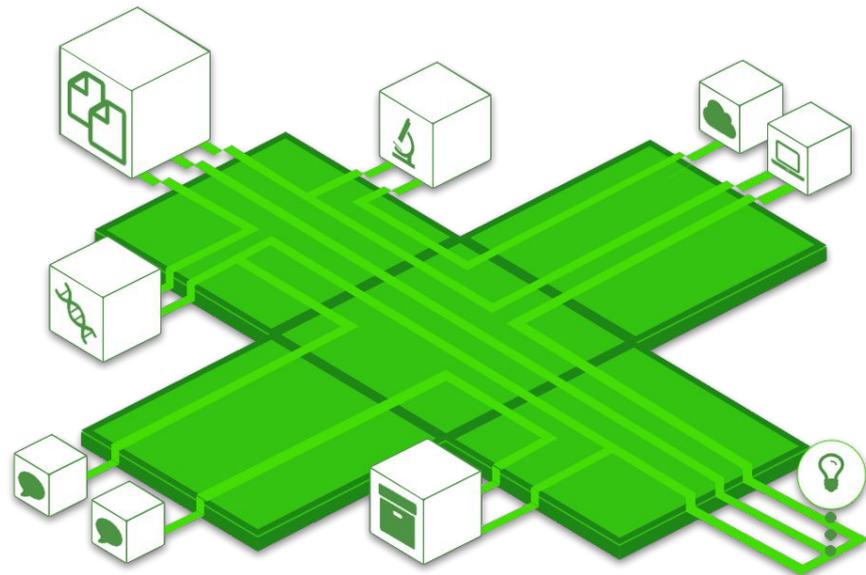
# A keystone for precision medicine in the community

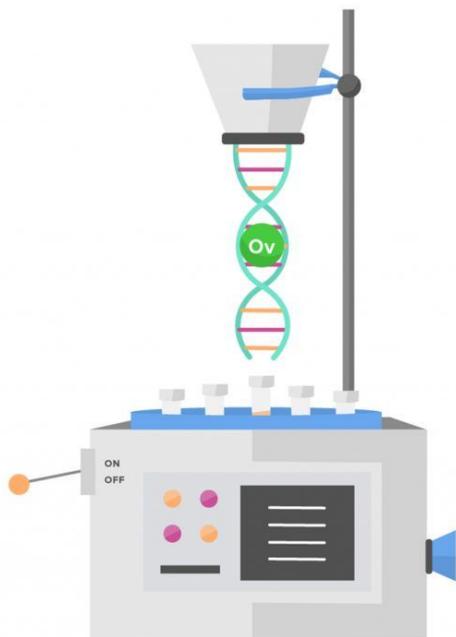


- **Actionable:** PharmD recommendation
- **Visionary:** Epidemic detection and management
- **Valuable:** Utilization reports and insights

# A Vision for the Future

Unlocking Innovation  
Partnering for Precision Care  
Moving at the speed of software





# Unlocking Innovation

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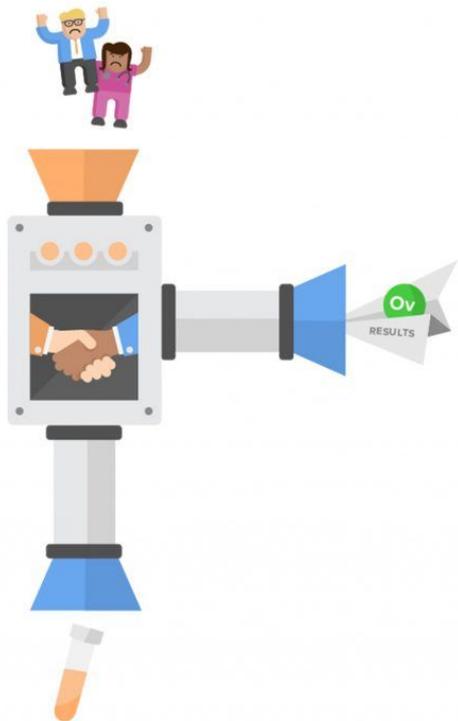
1. Identify gaps in community precision medicine
2. Leverage technology to service community needs by enabling:
  - a. New labs
  - b. New workflows
  - c. Proprietary diagnostics
3. Privacy-preserving big data to enable innovation at speed

# Partnering for Precision Care

## Improved Real World Data

- Health systems\*
  - Patient journey/cohort by x-ome
  - Precision treatment
  - Trial site validation
- Industry + patients
  - Just-in-time clinical trials
  - Shorten time from symptom to therapy
- Payors
  - Outcomes analysis
  - Cohort analysis by x-ome





# Consent

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## Labs are uniquely positioned

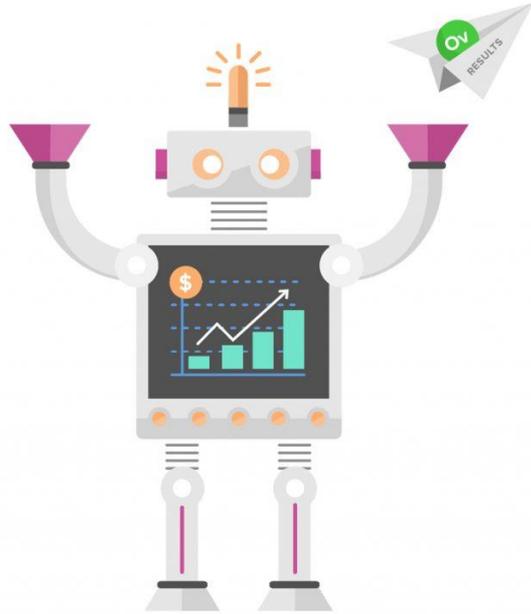
- Consent is already part of clinical workflow
- Established connections across value chain

## Society demands data privacy and consent

- GDPR, CA data privacy, etc.
- Portable Legal Consent

## Consent must be verifiably tracked with data

- Right to revoke consent
- Attestation of compliance

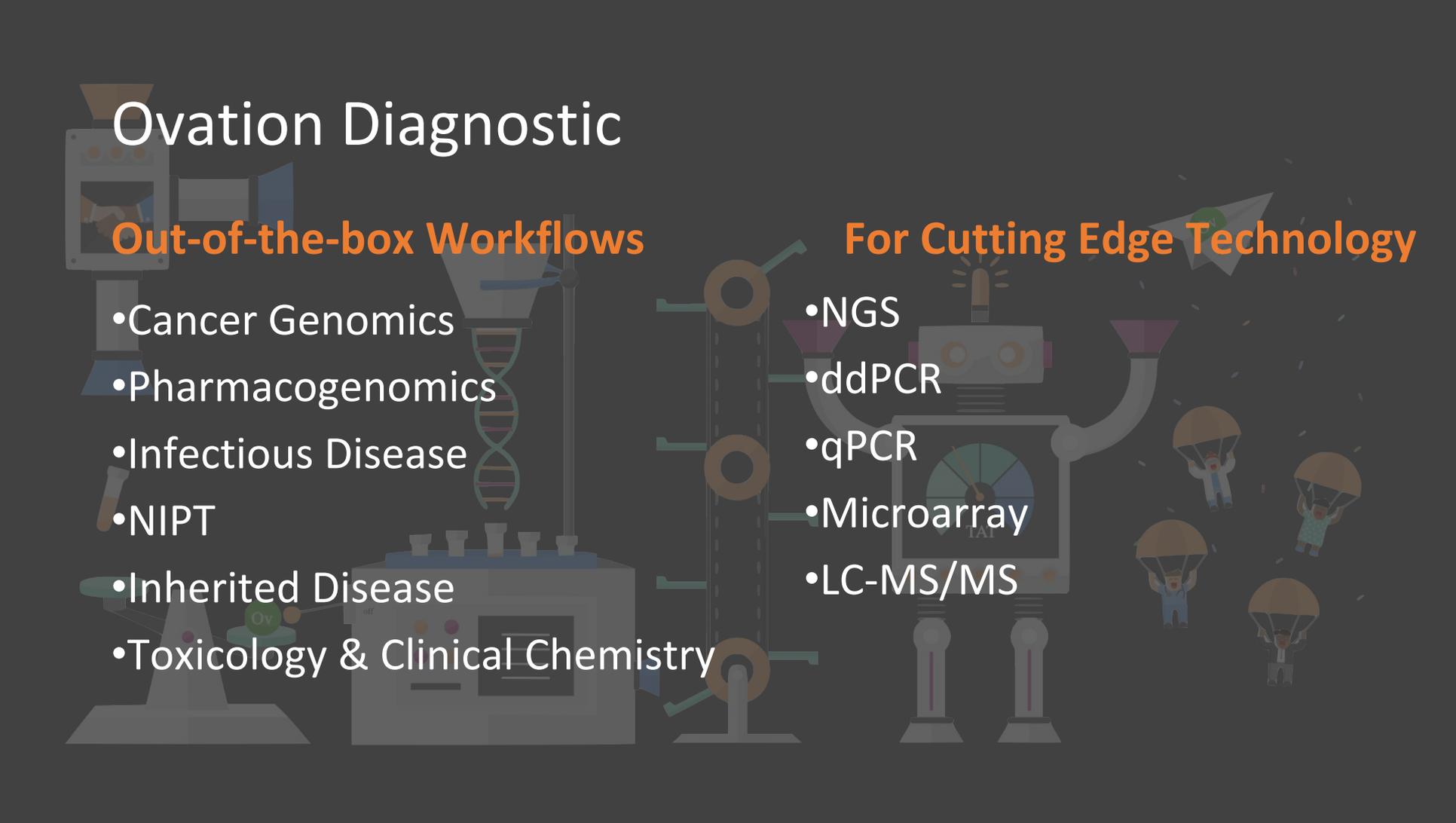


# Action Plan

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1. Identify the data needs of your provider community...
  - a. Journey/Outcomes analysis
  - b. Utilization
  - c. Bio markers
2. Build for Partnership in Precision Care
  - a. Consent
  - b. Data model
  - c. Infrastructure/informatics
3. Get started: new workflows...new informatics

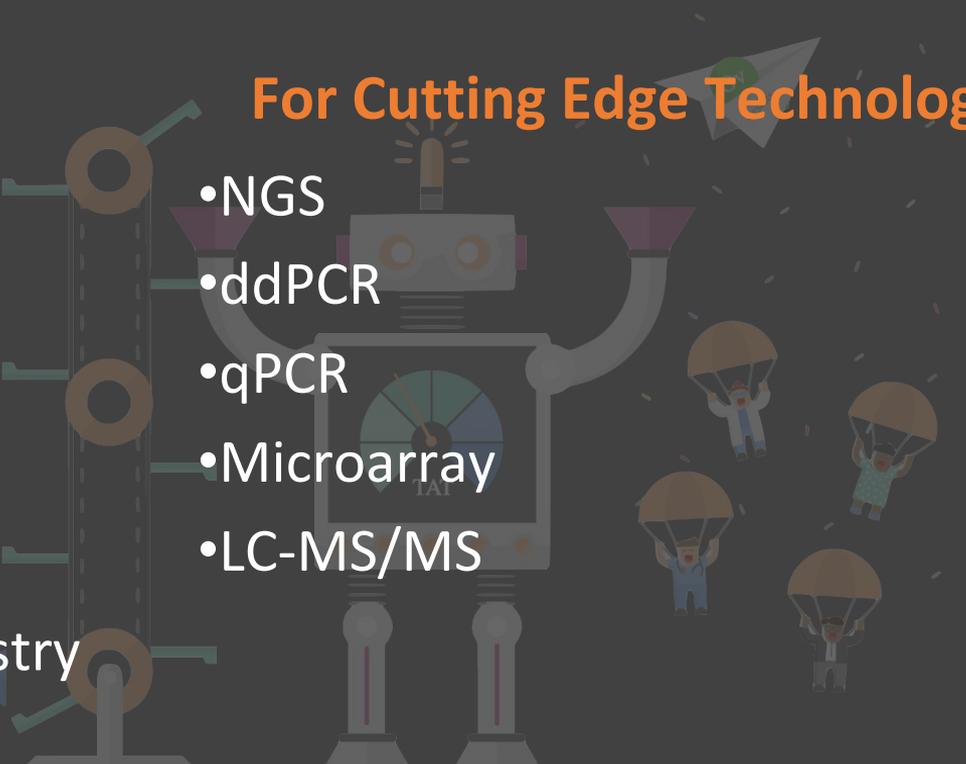
# Ovation Diagnostic



## Out-of-the-box Workflows

- Cancer Genomics
- Pharmacogenomics
- Infectious Disease
- NIPT
- Inherited Disease
- Toxicology & Clinical Chemistry

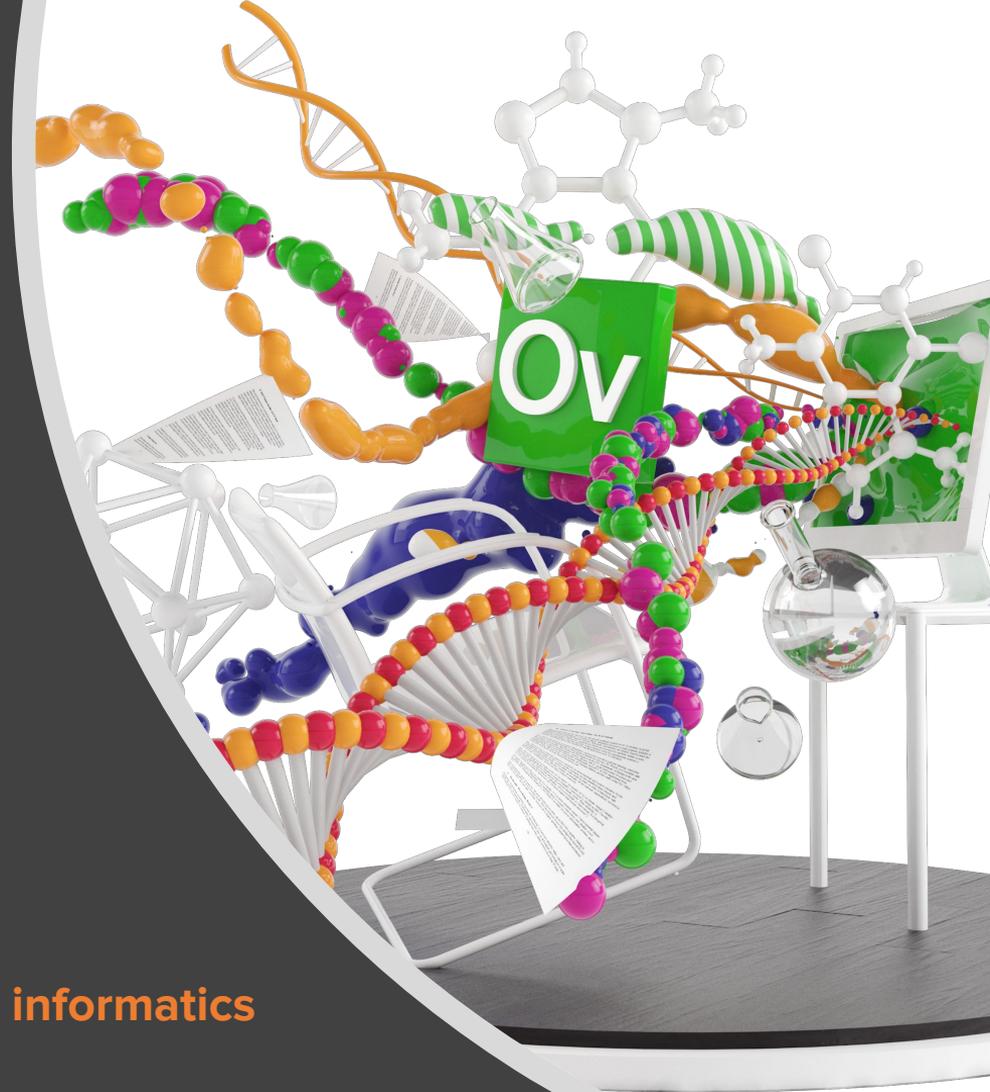
## For Cutting Edge Technology

- NGS
  - ddPCR
  - qPCR
  - Microarray
  - LC-MS/MS
- 

# Summary

- What is modern (next-generation) informatics?
- Why should you consider adopting a modern informatics stack?
- Case study: Volente Diagnostics
- Vision of the future
- Take Home Plan

**Unlock opportunity with modern informatics**





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