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Clinical Lab 2.0 Playbook:

Convergence of Diagnostics and Population Health

Project Santa Fe Foundation Workshop
March 2025

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Session Objectives

1. Understand the importance of the Clinical Lab 2.0 model
2. Describe “HOW TO” demonstrate Laboratory’s value
3. Examples of demonstration projects
4. Role of laboratory facilitated care models and interventions

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Reengineering the Future
Achieving Proactive Diagnostics

Adding Value with the Clinical Laboratory

- ✓Domain knowledge that can support clinical decision[1]
  - appropriate testing strategies
  - influence clinical decisions
  - impact patient outcomes
- ✓Challenges with existing health care infrastructure for improved patient outcomes[2]
  - not integrated, not acted upon, not correctly interpreted

1. *Sikaris KA. Enhancing the Clinical Value of Medical Laboratory Testing. Clin Biochem Rev. 2017 Nov; 38(3): 107-114.*
2. *Designing Care – Aligning the Nature and Management of Health Care by Richard MJ Bohmer*

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Value-based care = the right 'proactive diagnostics' with the right care, at the right time, in the right place, at the right cost

Well-care

Lab on the front-end

Sick-care

Lab on the back-end

Lab-faciliated Care Models

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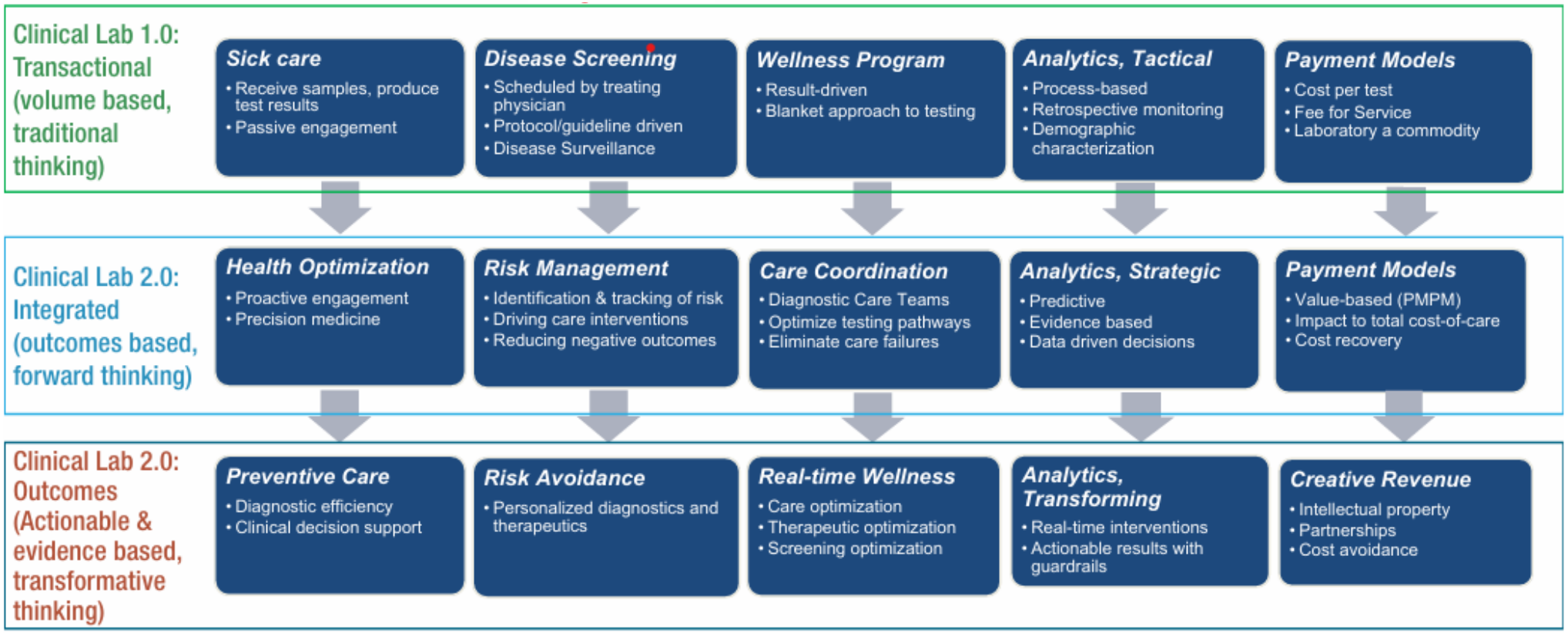
Moving from Clinical Lab 1.0 to Clinical Lab 2.0



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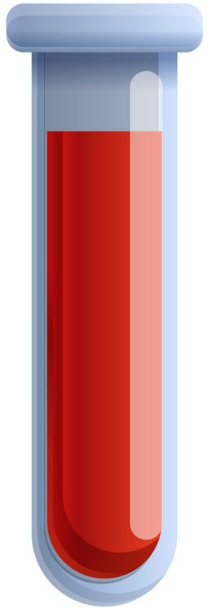
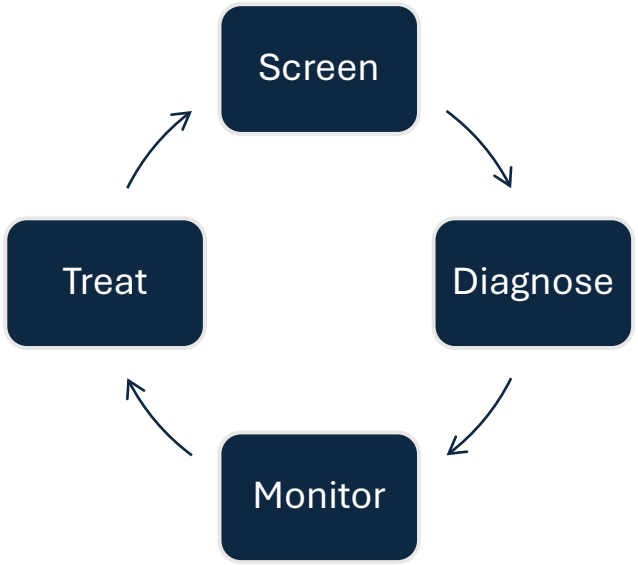
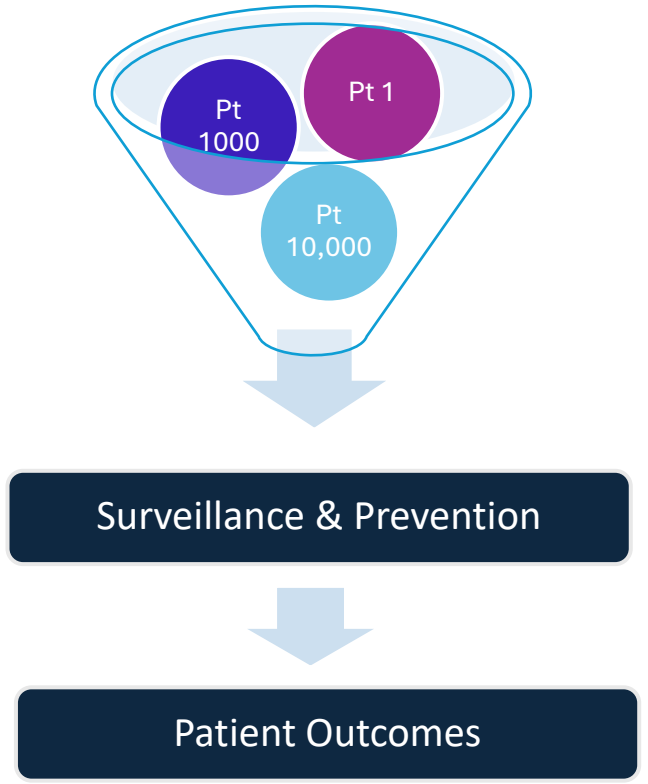
Laboratory's Evolving Role







Single test result
Lab 1.0

Longitudinal test result
from single patient

Longitudinal lab results from a population of patients
Lab 2.0

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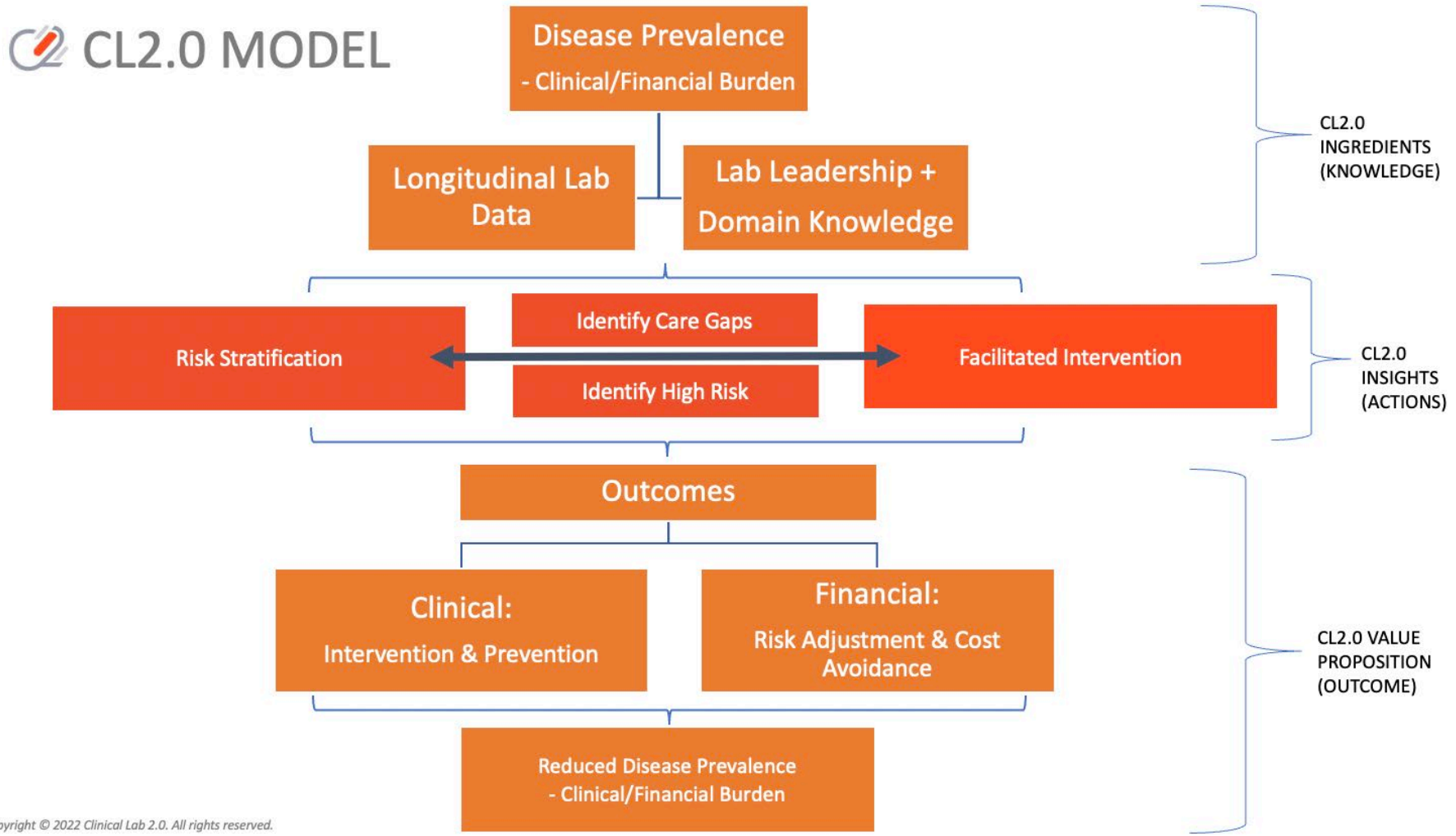
Lab's Role in Improved Clinical and Financial Outcomes
CL 2.0 Model



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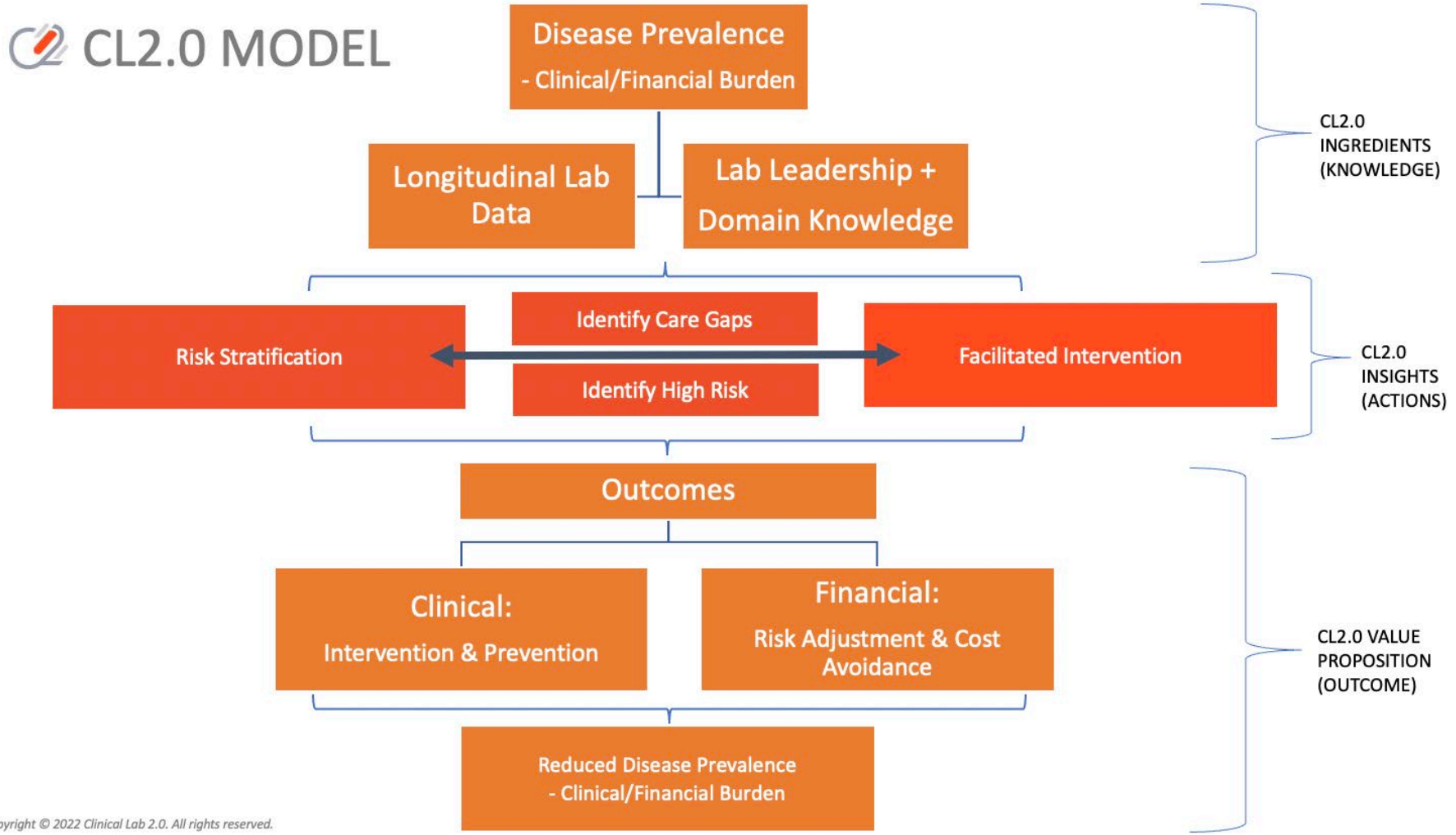
Lab's Role in Improved Clinical and Financial Outcomes Applying the CL 2.0 Model



- High prevalence conditions
- Laboratory Leadership
- Key Partnerships
  - Physician, Administrative, Payer champion
- Clinical Protocols
  - Testing cascade; diagnostic pathway
- Workflow & facilitated interventions
- Shared accountability
- Measurable and attributable outcomes
- Policy impacting clinical protocols & workflow

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Build a Toolbox to Implement Using the Clinical Lab 2.0 Model

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Develop a CL2.0 demonstration project Defining the **Ingredients**

Identify the ingredients you need in your toolbox for this project:

Why is the topic important, what data do you need, who are your partners

focused objectives

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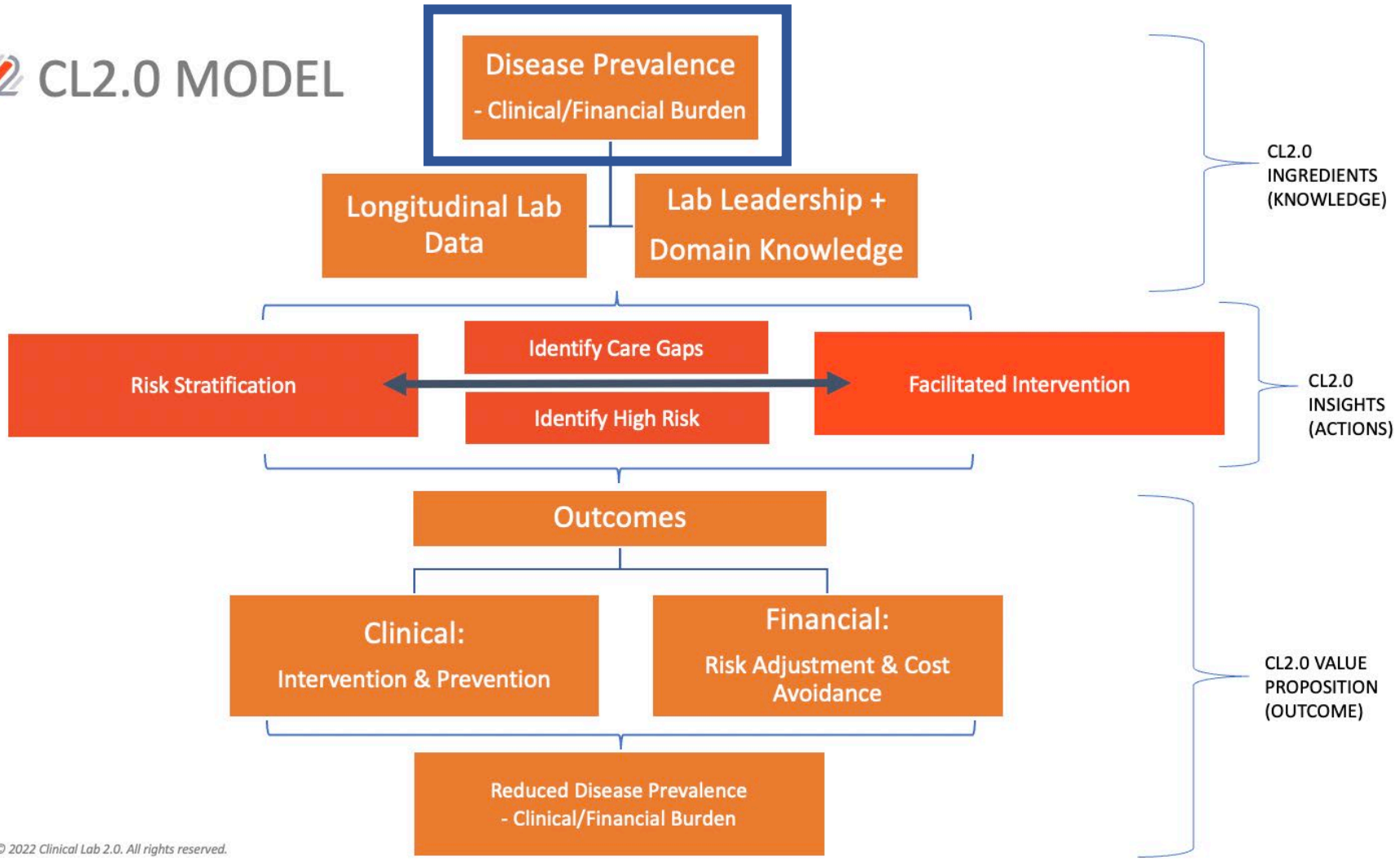
Lab's Role in Improved Clinical and Financial Outcomes Applying the CL 2.0 Model

CL2.0 MODEL



Toolbox

- ✓ 90% of costs involve 10% of diseases
- ✓ Not high-cost/low volume testing
- ✓ May be high volume testing
- ✓ May be inpatient or outpatient
- ✓ What are high cost/high prevalence conditions that impact your organization
- ✓ What problem(s) can you help solve with high prevalence conditions

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Chronic Kidney Disease Prevalence and Costs

- 37 million adults with CKD, most undiagnosed
- 40% with severely reduced kidney function are unaware
- Cost to treat Medicare beneficiaries with CKD
  - $87 billion (2019)

https://www.cdc.gov/kidneydisease/basics.html

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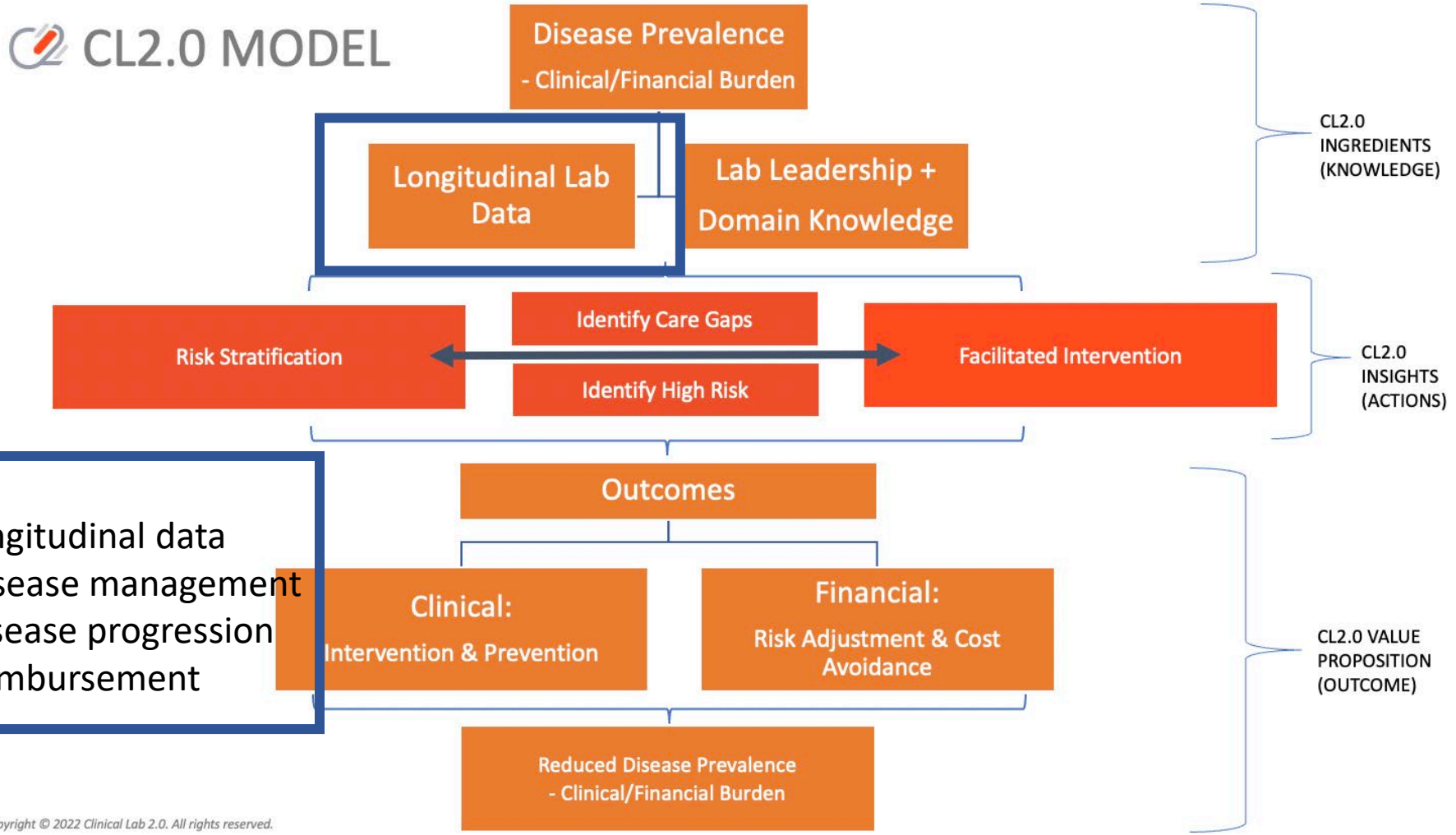
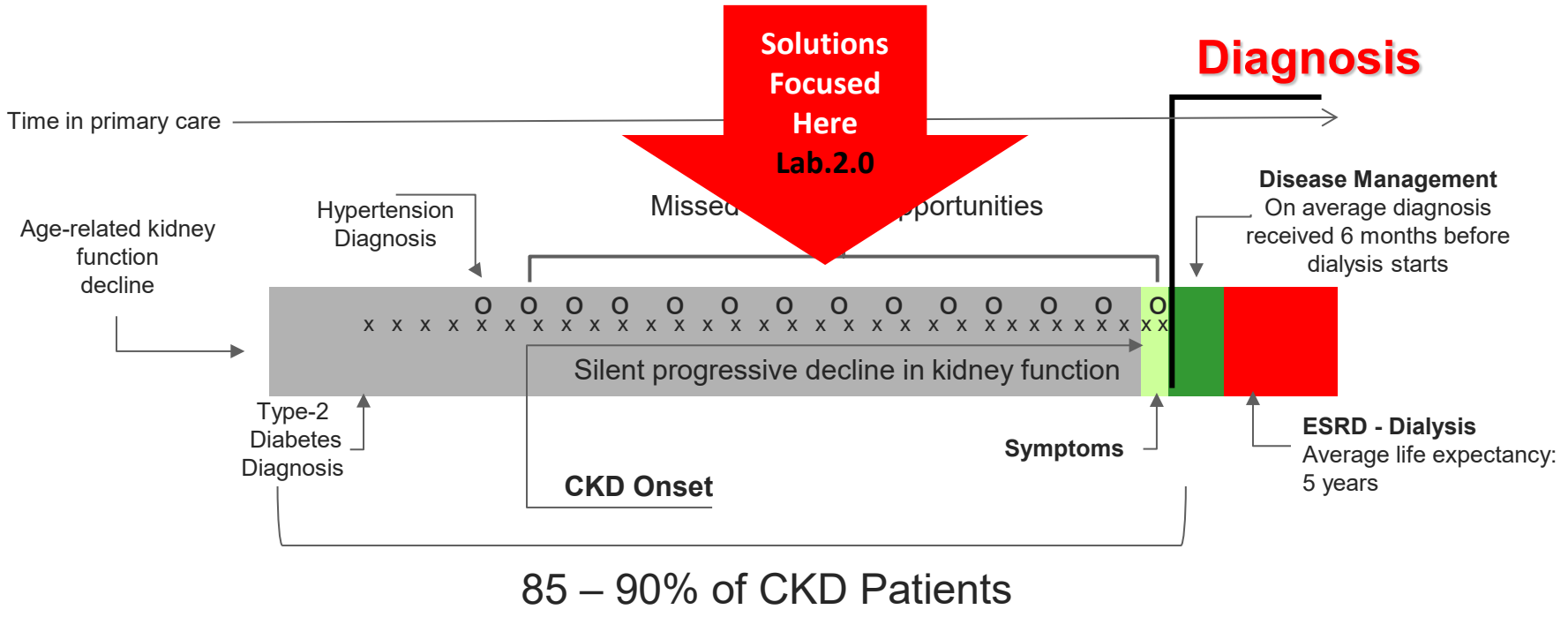
Lab's Role in Improved Clinical and Financial Outcomes
CL 2.0 Model



Toolbox

- ✓ Look at longitudinal data
- ✓ Chronic disease management
- ✓ Prior to disease progression
- ✓ Missed reimbursement

Role of CL 2.0 in Chronic Kidney Disease Care



Adapted from:

NATIONAL KIDNEY FOUNDATION®

Szczech, Lynda A, et al. "Primary Care Detection of Chronic Kidney Disease in Adults with Type-2 Diabetes: The ADD-CKD Study (Awareness, Detection and Drug Therapy in Type-2 Diabetes and Chronic Kidney Disease)." *PLOS One* 9(11); 2014:e110535 .

Tuot, Delphine S, et al. "Chronic Kidney Disease Awareness Among Individuals with Clinical Markers of Kidney Dysfunction." *Clin J Am Soc Nephrol* 6 (2011): 1838-1844.

Clinical Impact – Risk Stratification & Early Identification

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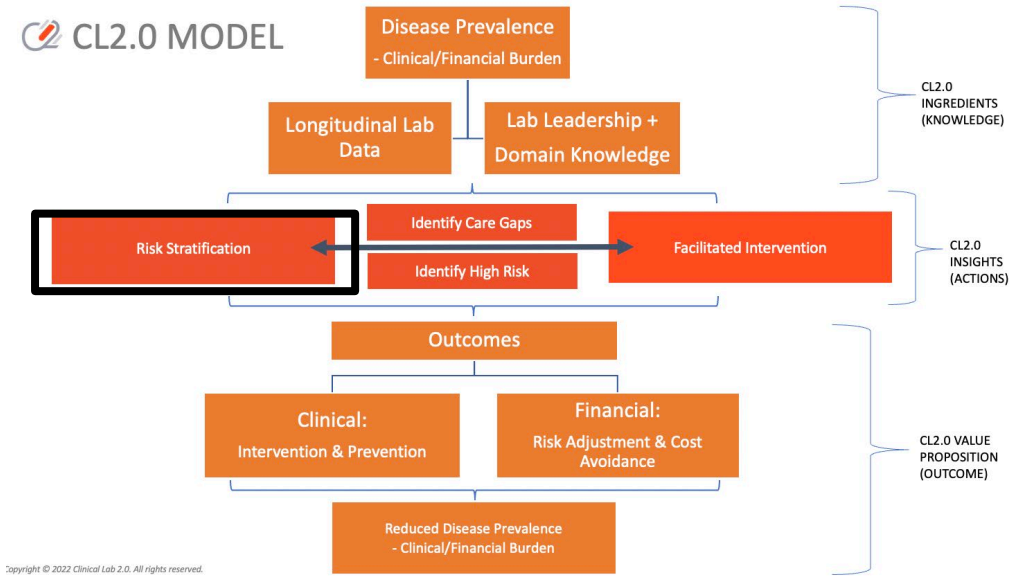

CKD Stage of CKD by eGFR (no ICD10) *	Institution A	Institution B	Institution C
3A	61%	58%	71%
3B	26%	31%	22%
4	13%	11%	7%

* Some patients were noted to progress to CKD Stage 5 from Stages 3B or 4 within the same year

Fung et al. BMC Nephrology https://doi.org/10.1186/s12882-024-03869-4

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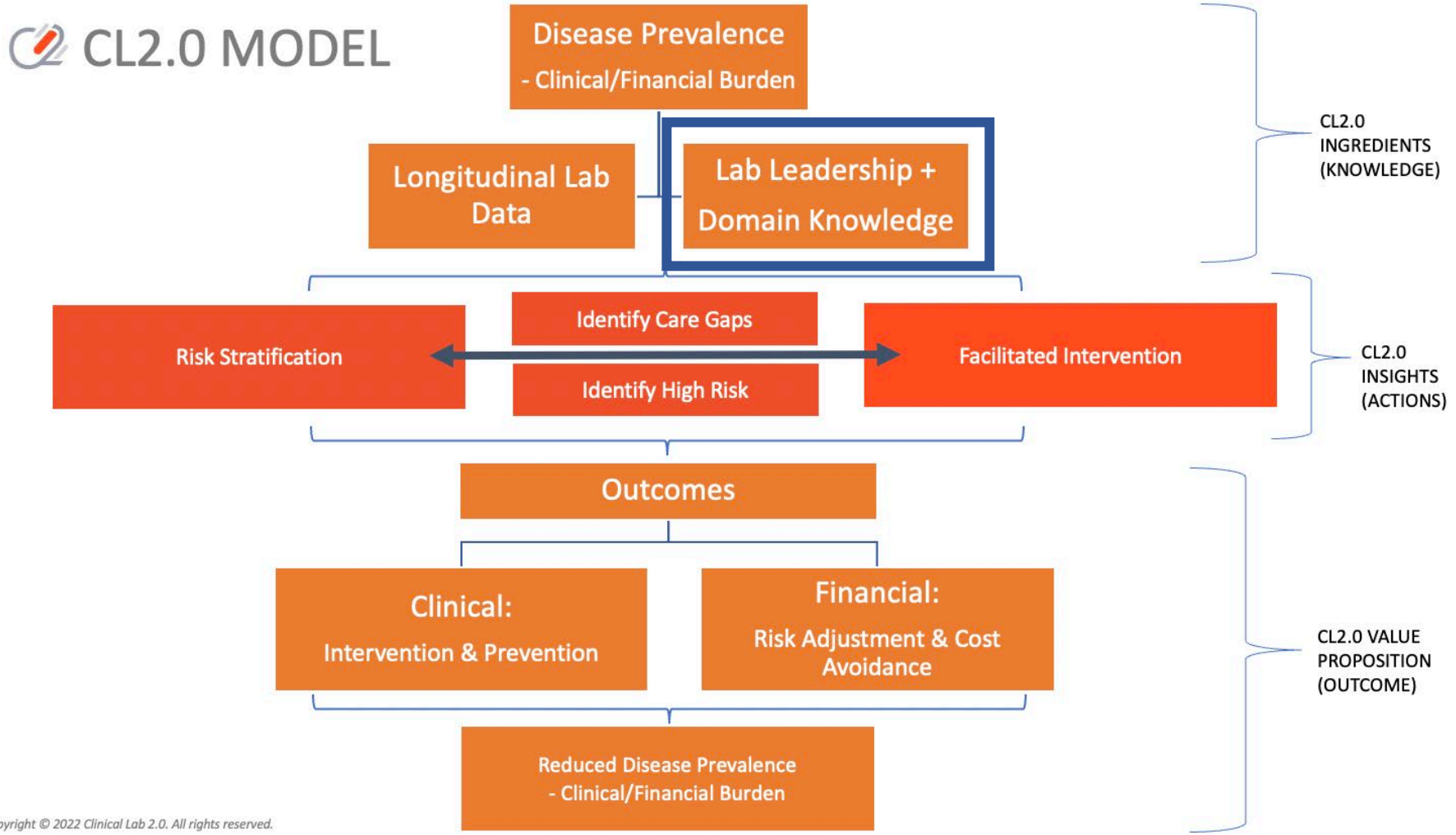
Lab's Role in Improved Clinical and Financial Outcomes Applying the CL 2.0 Model



Toolbox

Key partnerships:
physician,
administrators,
payers,
government,
national organizations,
quality groups

- ✓ What problem(s) are you solving for others?
- ✓ What knowledge do you have that others need?
- ✓ Get outside the lab
- ✓ Partners outside the lab with metadata
- ✓ Compare lab data to metadata

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Lab's Role in Improved Clinical and Financial Outcomes
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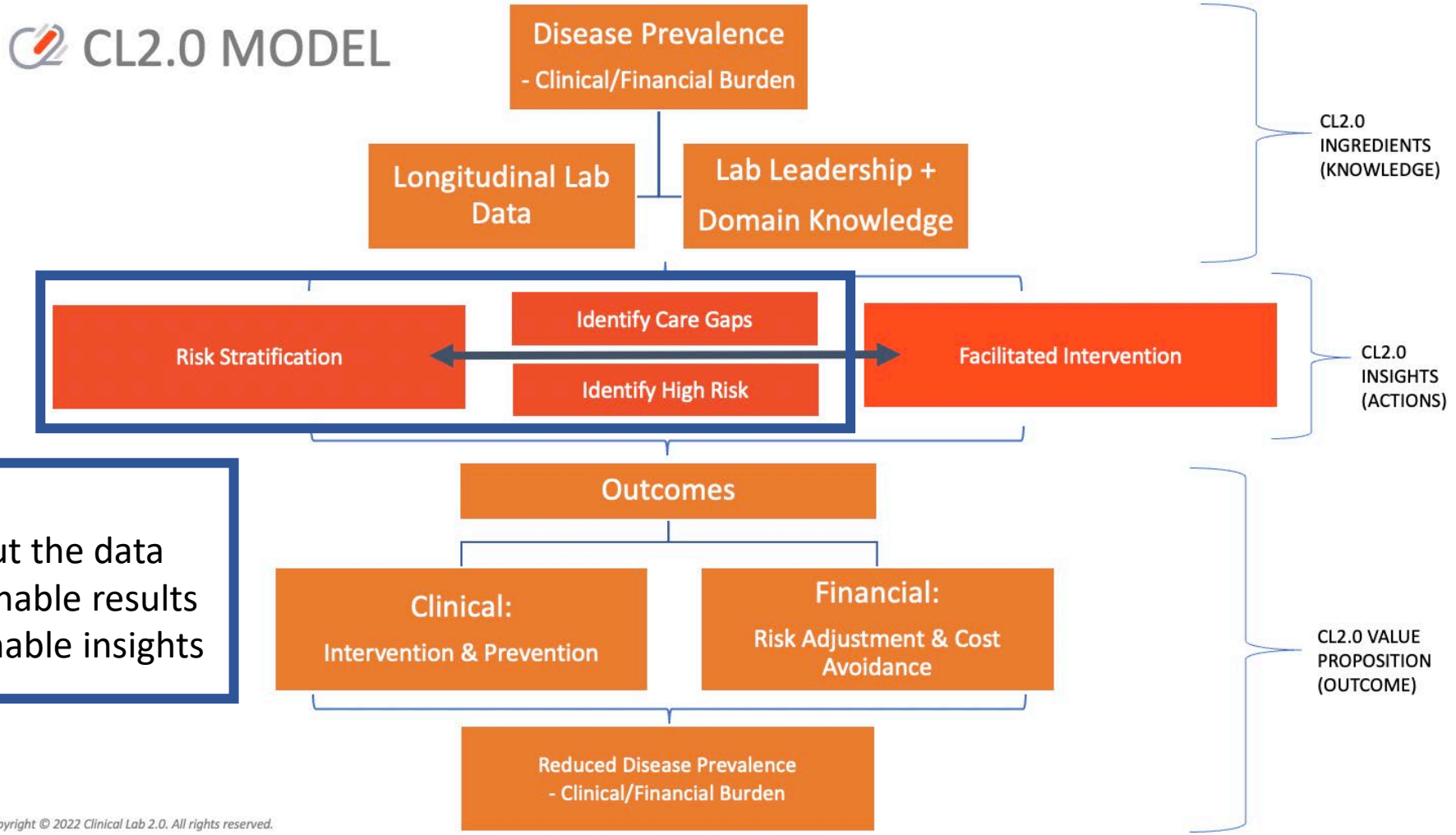

Toolbox

- ✓ Not just about the data
- ✓ Create actionable results
- ✓ Create actionable insights

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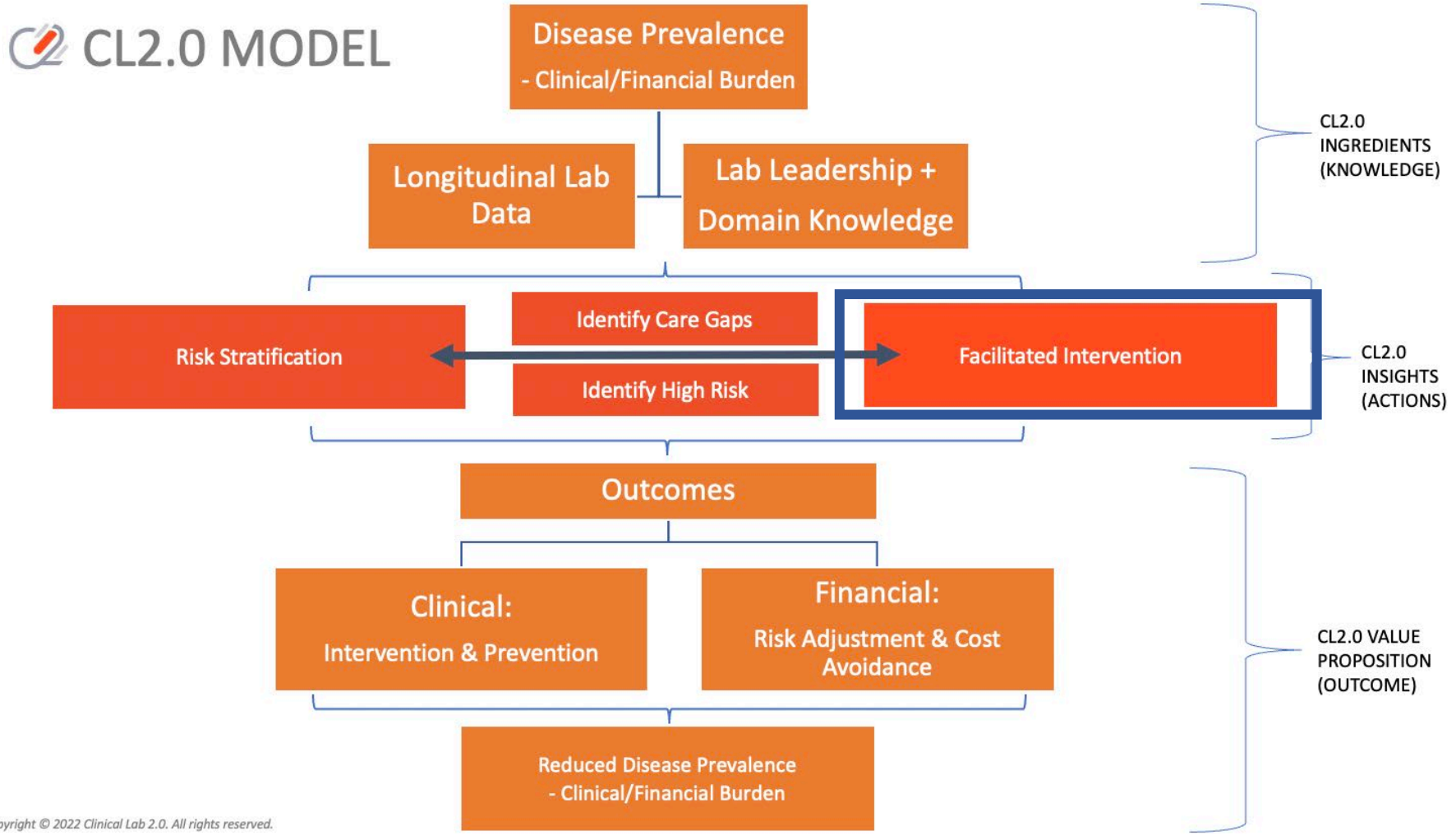

Toolbox

- ✓ Clinical Protocols
  - Testing cascades, diagnostic pathway, home monitoring
- ✓ Workflow & facilitated interventions
- ✓ Easy & integrated to support clinicians

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Develop a Facilitated Intervention

Interface with existing workflows

Imbed in current electronic tools,

Duck tape processes if needed for pilot

Leveraging Longitudinal Clinical Laboratory Results to Improve Prenatal Care

Richard VanNess, MS; Kathleen M. Swanson, MS; David G. Grenache, PhD; Mark Koenig, BS; Lauretta Dozier, RN; Amy Freeman, LPN; Eugene Sun, MD, MBA; Craig Nelson, MA; and Michael J. Crossey, MD, PhD

Am J Manag Care. 2021 Feb; 27: 60-65

Provide a weekly laboratory-generated report to the state Medicare Care Coordinators, identifying pregnant Women with care gaps in prenatal laboratory testing; initiate prenatal care through targeted intervention.

TABLE 3. Secondary Outcomes

	Entire study population (N = 1355)	Group A: evidence of ongoing prenatal care (n = 451)	Group B: limited to no evidence of ongoing prenatal care (n = 904)
Women with at least 1 emergency department visit, n (%)	280 (20.7)	78 (17.3)	202 (22.3)
Births with known gestational age, n	159	88	71
Preterm births, n (%)[a]	24 (15.1%)	10 (11.4%)	14 (19.7%)
NICU admissions, n (%)[b]	66 (15.2%)	19 (10.7%)	47 (18.2%)
NICU length of stay in days, mean (range)	13.5 (0.13-94.2)	16.6 (0.29-94.1)	12.3 (0.13-64.2)

NICU, neonatal intensive care unit.

[a]Denominator is number of births with known gestational age.

[b]Denominator is the 435 infants with known location of first phlebotomy. Group A: n = 177; group B: n = 258.

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Develop a CL2.0 demonstration project
Defining the **Insights**

What risk(s) can you identify,
what care gaps can you close,
what high risk patients can be found,
what reimbursement is missing?

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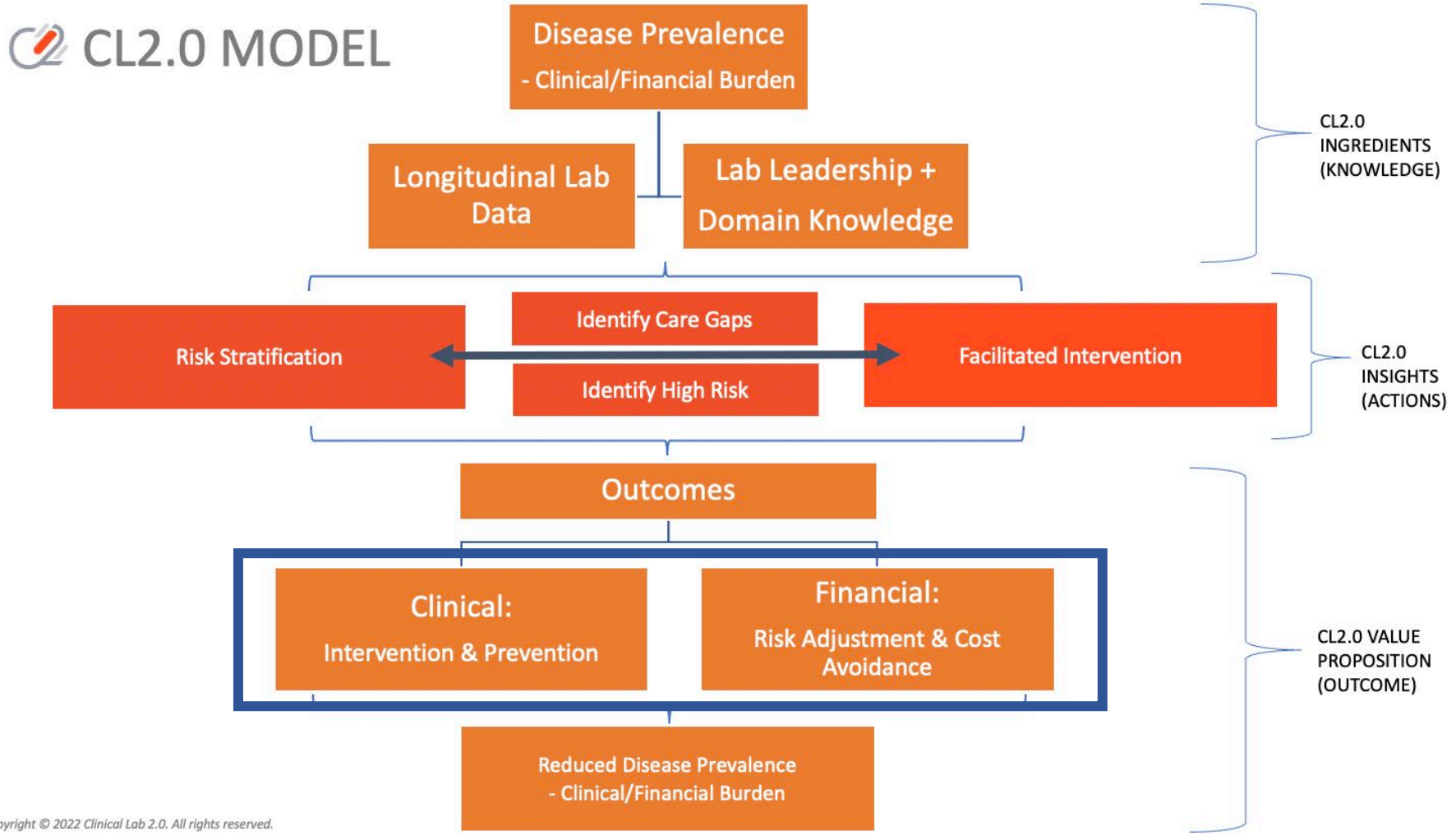

Toolbox

- ✓ Attribution to the laboratory's action
- ✓ Measurable and attributable outcomes
- ✓ Policy impacting clinical protocols & workflow
- ✓ Cost of care
- ✓ Reduce costs and/or improve revenue capture

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Defining **Clinical Outcomes**

Risk stratification,

Gaps in care,

Identification of high-risk patients,

Guideline based care recommendations.

Clinical Impact – Care Gaps

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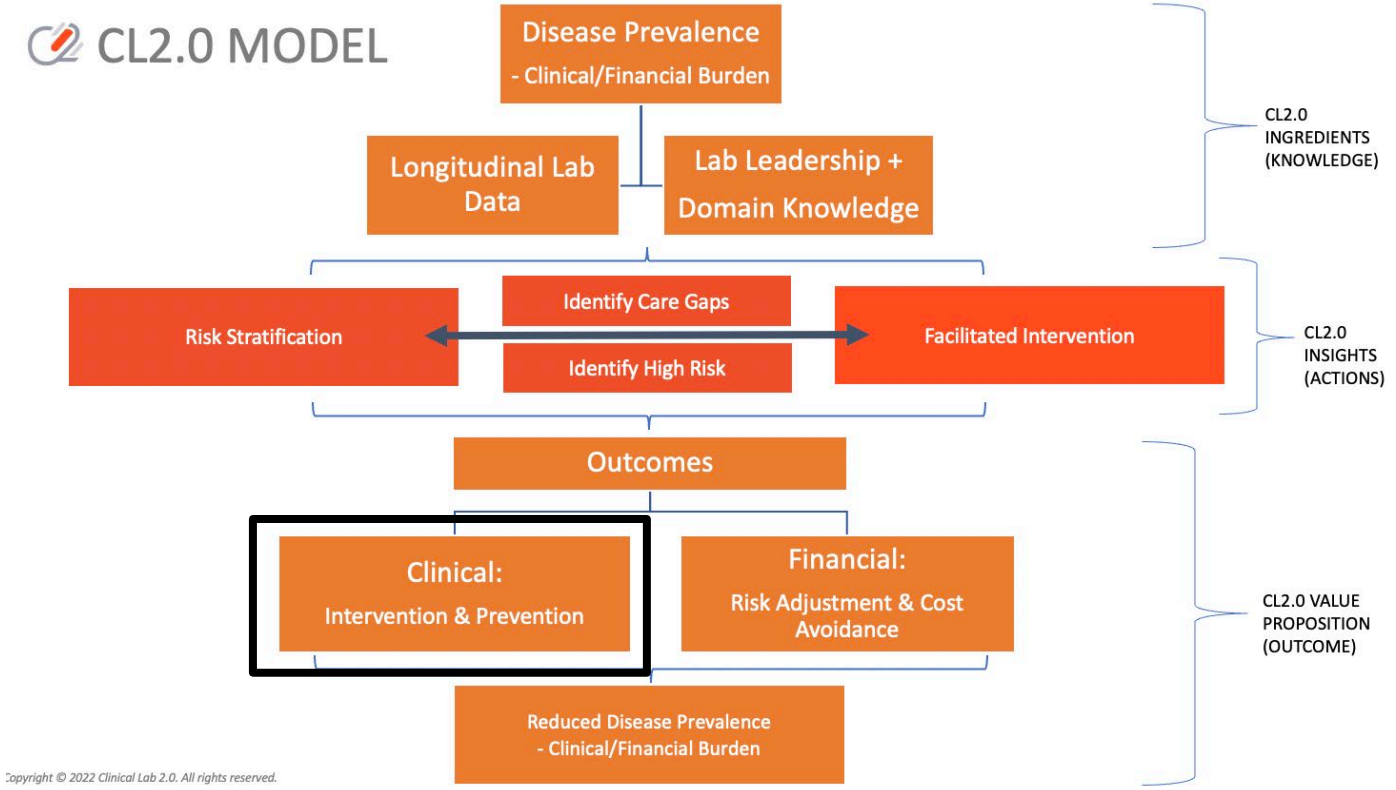

	Institution A	Institution B	Institution C
Diabetics (HbA1c >/= 6.5 with NO screening for CKD	59%	83%	77%

Fung et al. BMC Nephrology https://doi.org/10.1186/s12882-024-03869-4

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Defining **Financial Outcomes**

Support reimbursement strategies by identifying risk,
Improve billing capture,
Identify disease early,
Improve quality metrics.

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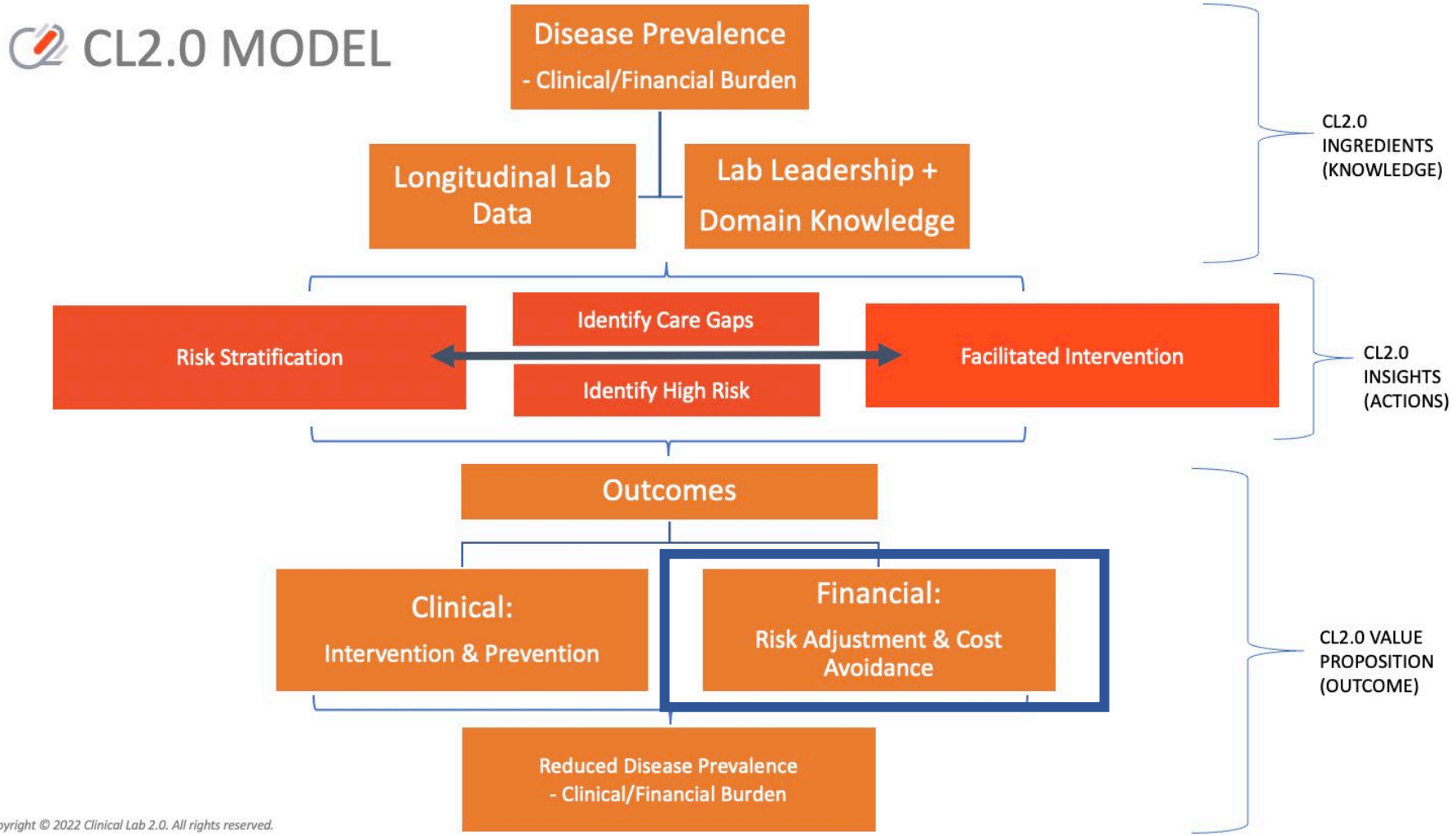

Toolbox

- ✓ Risk adjusted reimbursement such as Hierarchical Condition Categories (HCCs)
- ✓ Missing ICD-10 codes
- ✓ Reduced ER visits and hospitalizations
- ✓ Early recognition of costly conditions
- ✓ Inadequate care with downstream costs

Financial Impact – Missed Economic Opportunities not Identified in Claims Data

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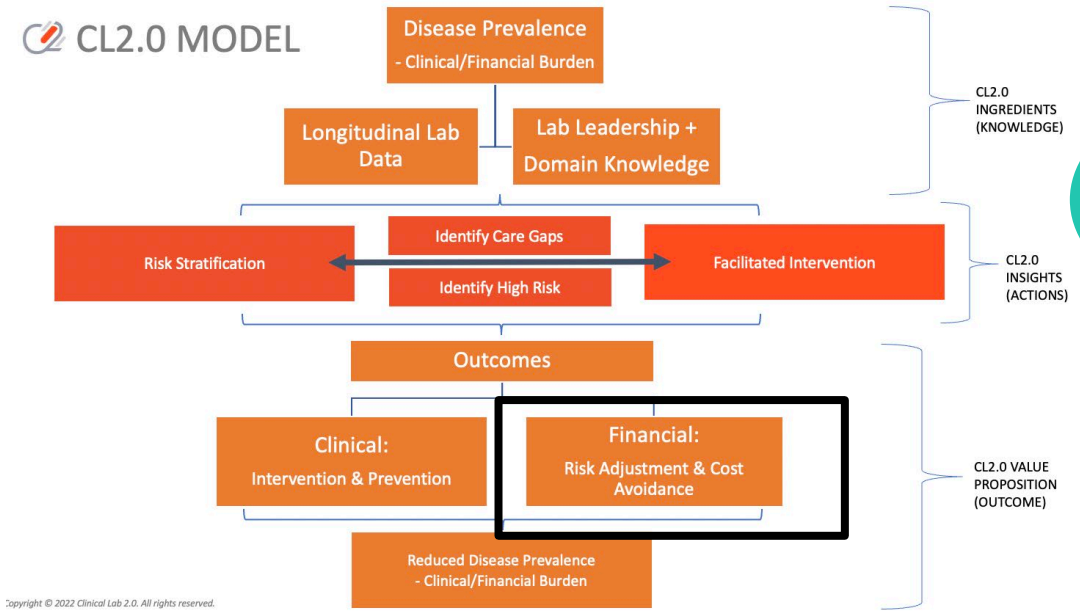

How CKD is identified?	Institution A	Institution B	Institution C
Lab Results Only	78%	32%	66%
Both Lab + Dx Code	4%	19%	22%
Dx Code Only	18%	49%	11%

Fung et al. BMC Nephrology https://doi.org/10.1186/s12882-024-03869-4

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2021 ESTIMATED IMPACT -
ACROSS 3 STUDY LOCATIONS

3,246 patients identified using lab data & at risk of dialysis
$ 2.85 MILLION DOLLARS unrealized reimbursement

Assumptions:
- 2021 annual enrollments for Medicare Advantage/CA as % of 2020 population
- 2021 reimbursement rates for Medicare Advantage/ACA
- Gaps in CKD identification from PSFF CKD study

UNREALIZED REIMBUSEMENT from UNDIGNOSED CKD across 3 study LOCATIONS in 2021		
	Unrealized Risk Adjustment Reimbursement	# Patients at Risk of Dialysis
Medicare Stage 3	$1,665,146	2866
Medicare Stage 4	$619,944	312
ACA Stage 4	$569,636	68

KFF - Health Policy Analysis, Polling, Journalism and Social Impact Media Accessed March 1, 2023

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Providing Thought Leadership - Lab Initiated or Lab Facilitated Care Models

- *What are these and how can they be used?*

Evidence based guidance

Focus on high prevalence and/or high risk clinical condition

Provide "HOW TO" recommendations

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Conclusion

- Laboratory data can provide critical insights into Population Health
- Multi-institutional collaborations demonstrate regional variability and opportunity
- *Acting* upon these insights requires initiative, leadership, and partnership

The lab's potential impact doesn't end when we release a result;

rather that's where it begins.

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