



# Value Starts with People:

Turning AI Into Impact in  
Clinical Data Analytics

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**Here to Dare.**

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What is going on  
in the industry?

# We are at an inflection point.



2022, van Dorn A., 'COVID-19 and readjusting clinical trials'

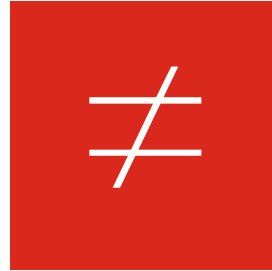
2026, DrugPatentWatch., 'The \$236 Billion Cliff: How Pharma Loses Its Blockbusters—and What Replaces Them'

3 2025, IFPMA., 'Always Innovating Pharmaceutical Industry Facts & Figures'

# The stakes are high.



The **cost** of  
**inaction** is  
growing



Clear **ROI gap** when  
tech scales faster  
than adoption



Every inefficiency  
**delays** patient  
impact

The regulatory bodies are signaling.

“

Early-phase clinical trials are a bottleneck in drug development... with improvements in AI and data science, sponsors and trial sites have the opportunity to conduct real-time trials in a way that enhances safety monitoring and radically increases efficiency.”

(FDA, 2026)

AI use  
cases  
are  
scaling.

90%

Life Sciences organizations are  
increasing AI investments

(Gartner, 2025)

500+

submissions used  
AI components  
since 2016

(FDA, 2025)

## Data Management

- Medical Coding
- Automated Data Review
- Query Management
- Standards Mapping

## Clinical Programming

- Code Generation (SAS/R)
- SDTM/ADaM Dataset Creation
- Automated Validation & QC
- TLF Generation & Reporting Automation

## Data Science

- Advanced Insights Generation
- Trial Design Optimization
- Patient Identification
- Risk-Based Monitoring

## Biostatistics

- Automated SAP Drafting
- Signal Detection & Safety Monitoring
- Predictive Analytics
- Decision Support

AI is  
redefining  
clinical data  
workflows.

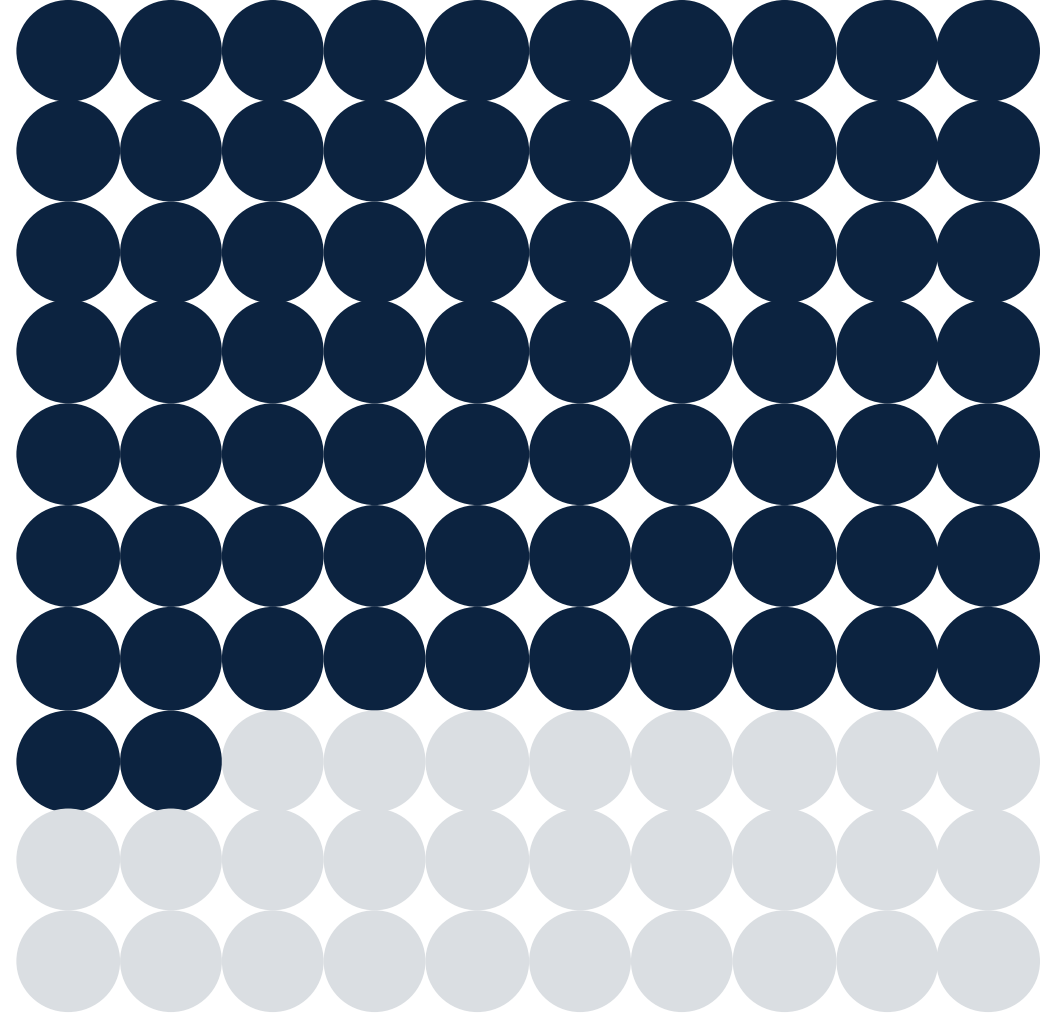
VALUE CAPTURE IS UNEVEN

But... AI  $\neq$  ROI

72%

of Life Sciences CIOs have reported that their organizations **broke even** or have **lost money** on their **AI investments**.

(Gartner, 2025)

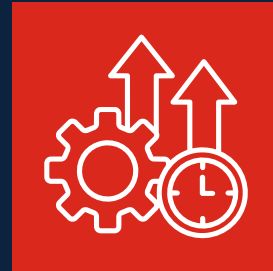




When AI  
scales but  
adoption  
doesn't, we  
lose...



Momentum



Productivity

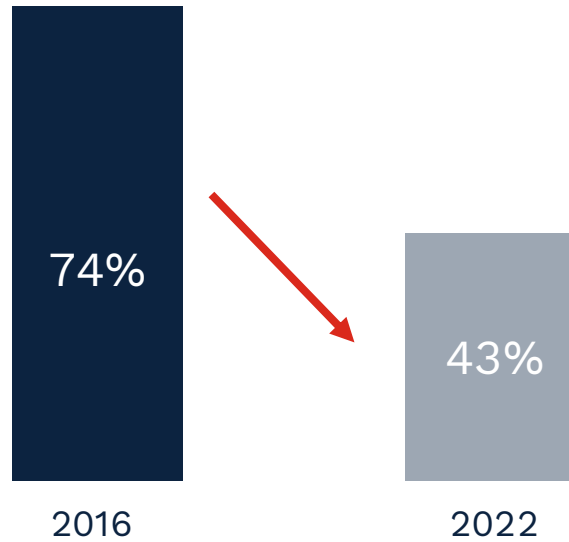


Value

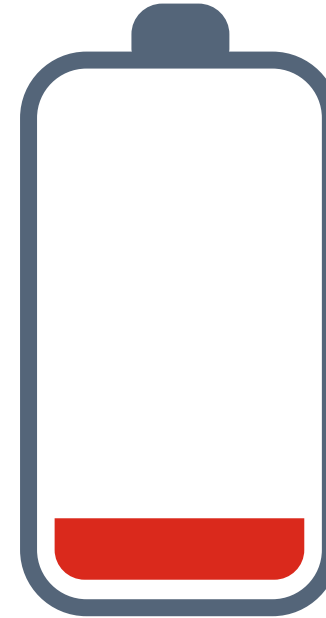
Why are we  
investing but not  
seeing value?

## HUMAN BEHAVIOR

Adoption is not a technology problem.  
It is a **human behavior** problem.



% of employees willing to adopt new behaviors to support organizational changes has **declined**



With the average employee now experiencing **10 planned changes** annually, people are running on empty...

# Human contribution is shifting...

## From

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- **Manual review** of listings, identifying anomalies, raising queries.
- **Writing** code, transforming data, **building** SDTM/ADaM datasets.
- **Executing** QC checks and **comparing** outputs.
- **Producing** TLFs, define.xml, specifications, and supporting documentation.
- **Managing** tasks, handoffs, and study deliverables.

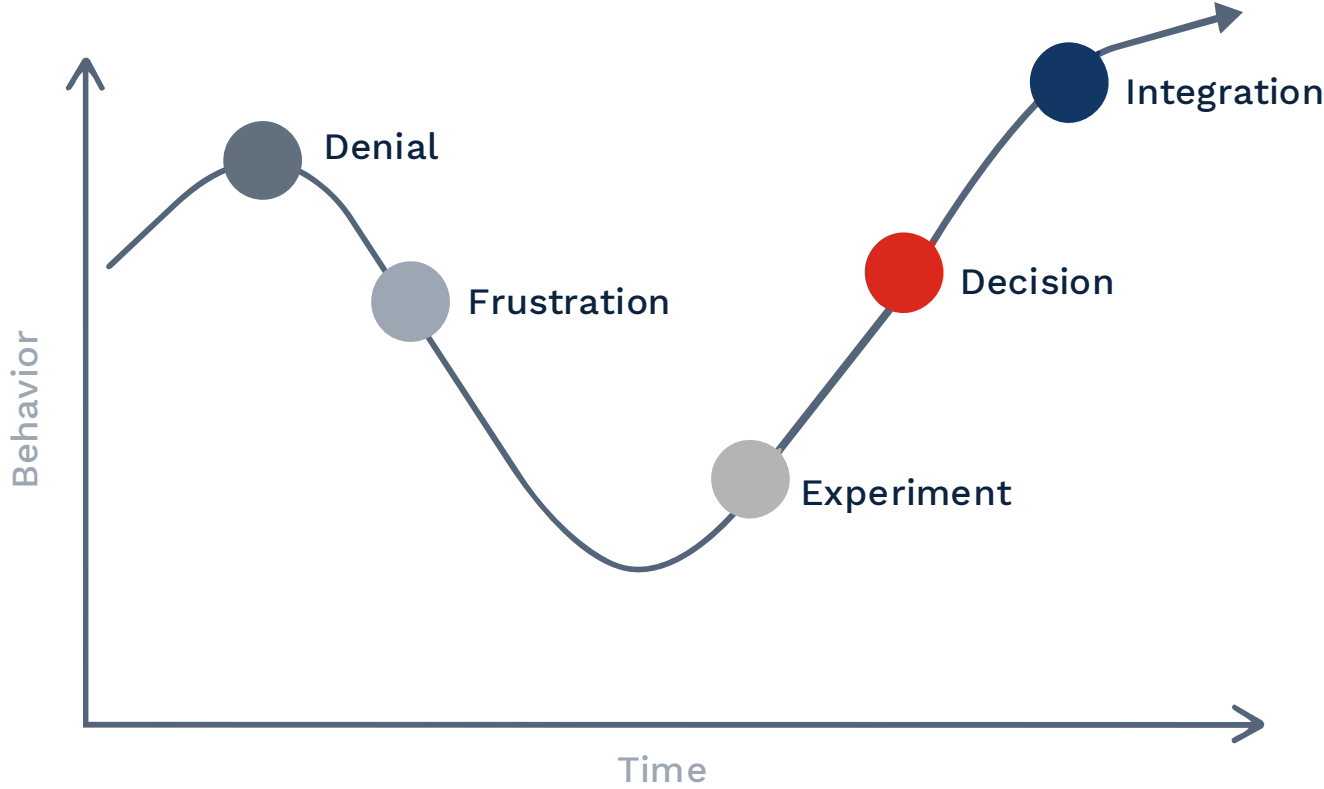
## To

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- **Overseeing** AI-driven review, assessing risk, and determining what matters most.
- **Directing** AI-generated code and **validating** logic.
- **Challenging** outputs, **investigating** exceptions, and **governing** quality standards.
- **Interpreting** results, ensuring narrative consistency, and verifying regulatory readiness.
- **Orchestrating** end-to-end workflows across people, process, data, and AI.

HUMAN BEHAVIOR

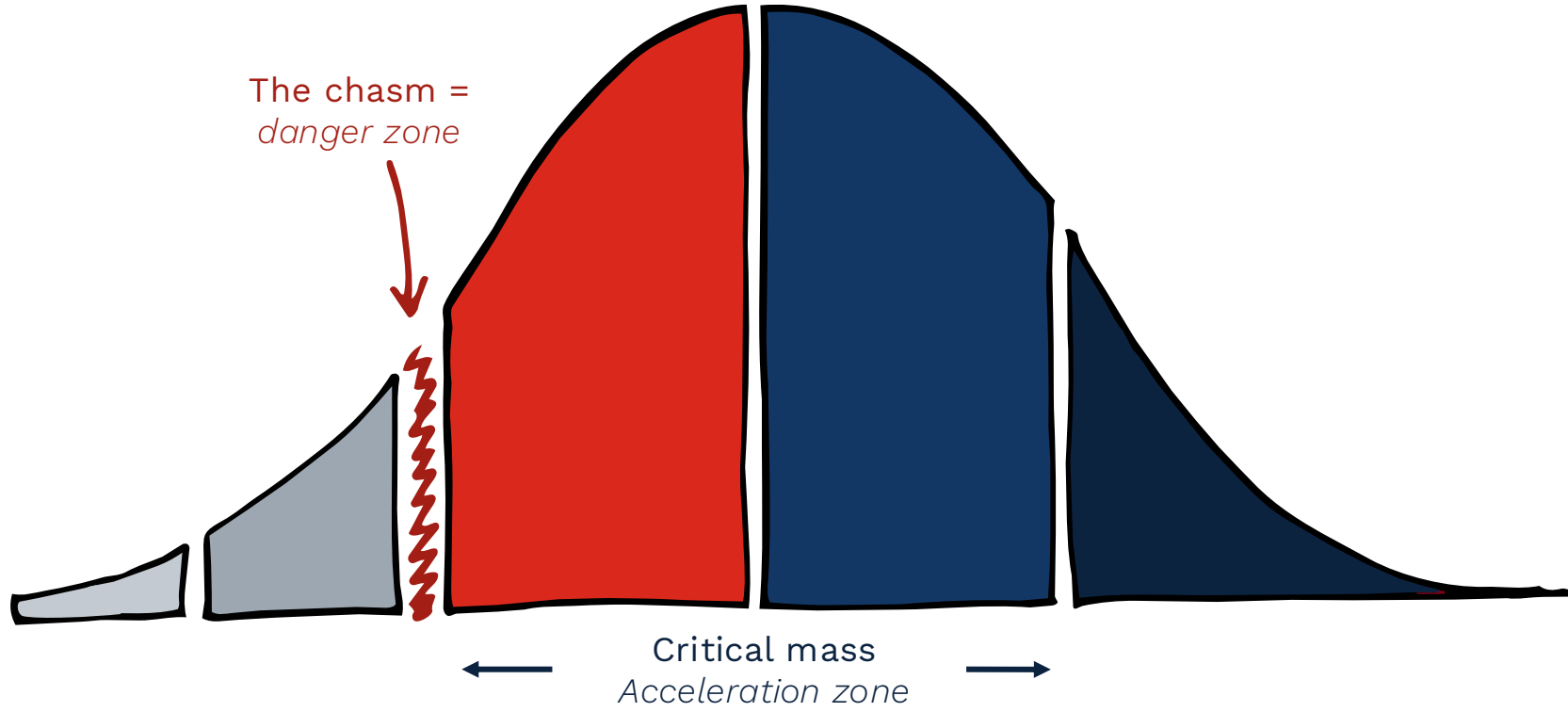
Before people embrace change,  
they **navigate** it.



- Create Alignment
- Spark Motivation
- Maximize Communication
- Develop Capability
- Share Knowledge

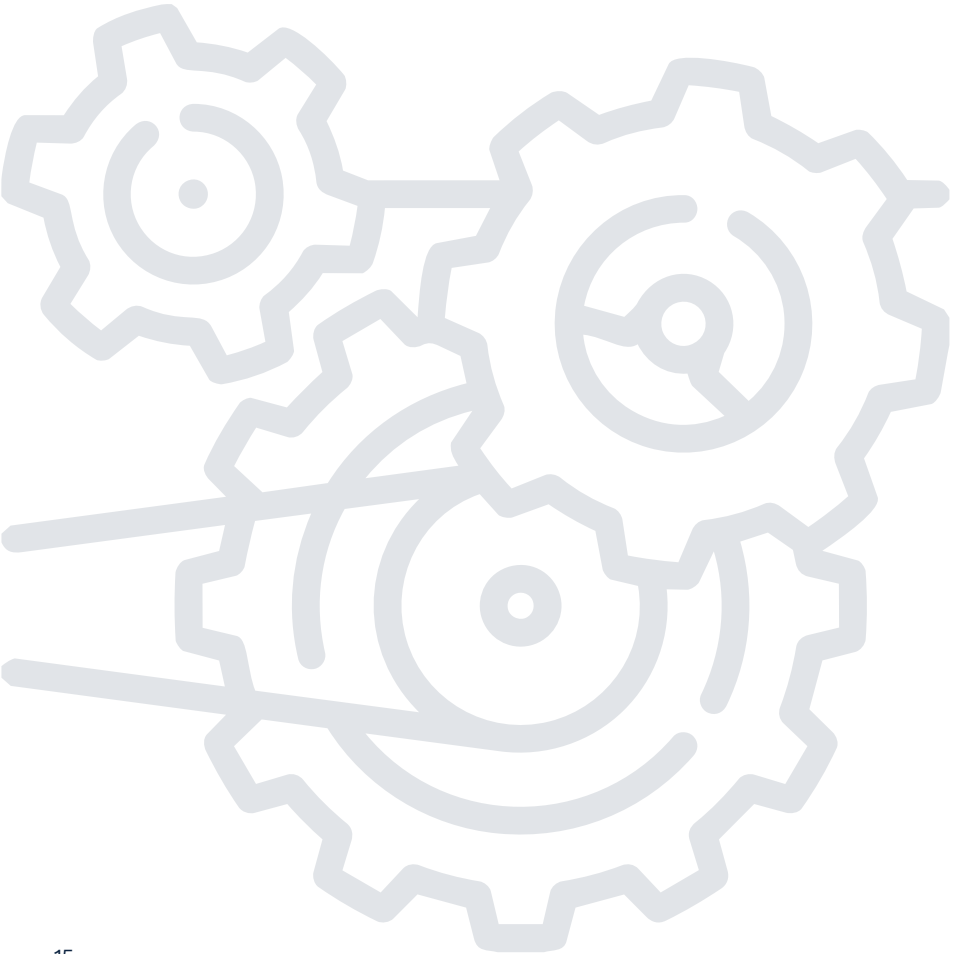
HUMAN BEHAVIOR

An innovation diffuses when there is a shift in perceived value, trust, and buy-in.



|            |                |                |               |          |
|------------|----------------|----------------|---------------|----------|
| Innovators | Early Adopters | Early Majority | Late Majority | Laggards |
| 2.5%       | 13.5%          | 34%            | 34%           | 16%      |

People are the multiplier.



People are not a barrier to AI value  
— they are the mechanism  
for realizing it.

## HUMAN BEHAVIOR

This requires  
us to think  
and act  
differently...



## Accountability

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Own outcomes, trust, and quality

## Agility

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Adapt quickly to changing technologies, roles, and ways of working

## Systems Thinking

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See beyond individual tasks to the end-to-end workflow

## Adaptability

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Adjust thinking and approach as situations evolve

## Curiosity

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Continuously learn and experiment



# What we need to do now?

# When work changes, organizations need to change too.

## Roles need to be evolved

- Human contribution shifts from execution to interpretation, judgement, and decision-making.
- New capabilities are required, including AI literacy, critical thinking, and navigating ambiguity.

## Ways of working need to be reimagined

- AI becomes embedded in data review, validation, documentation, and analysis workflows.
- Manual, task-based activities become increasingly automated and orchestrated.

## Op models need to be transformed

- Teams become more integrated across Data Management, Programming, Statistics, Data Science, and Technology.
- Decision making shifts closer to AI-enabled insights and real-time information.

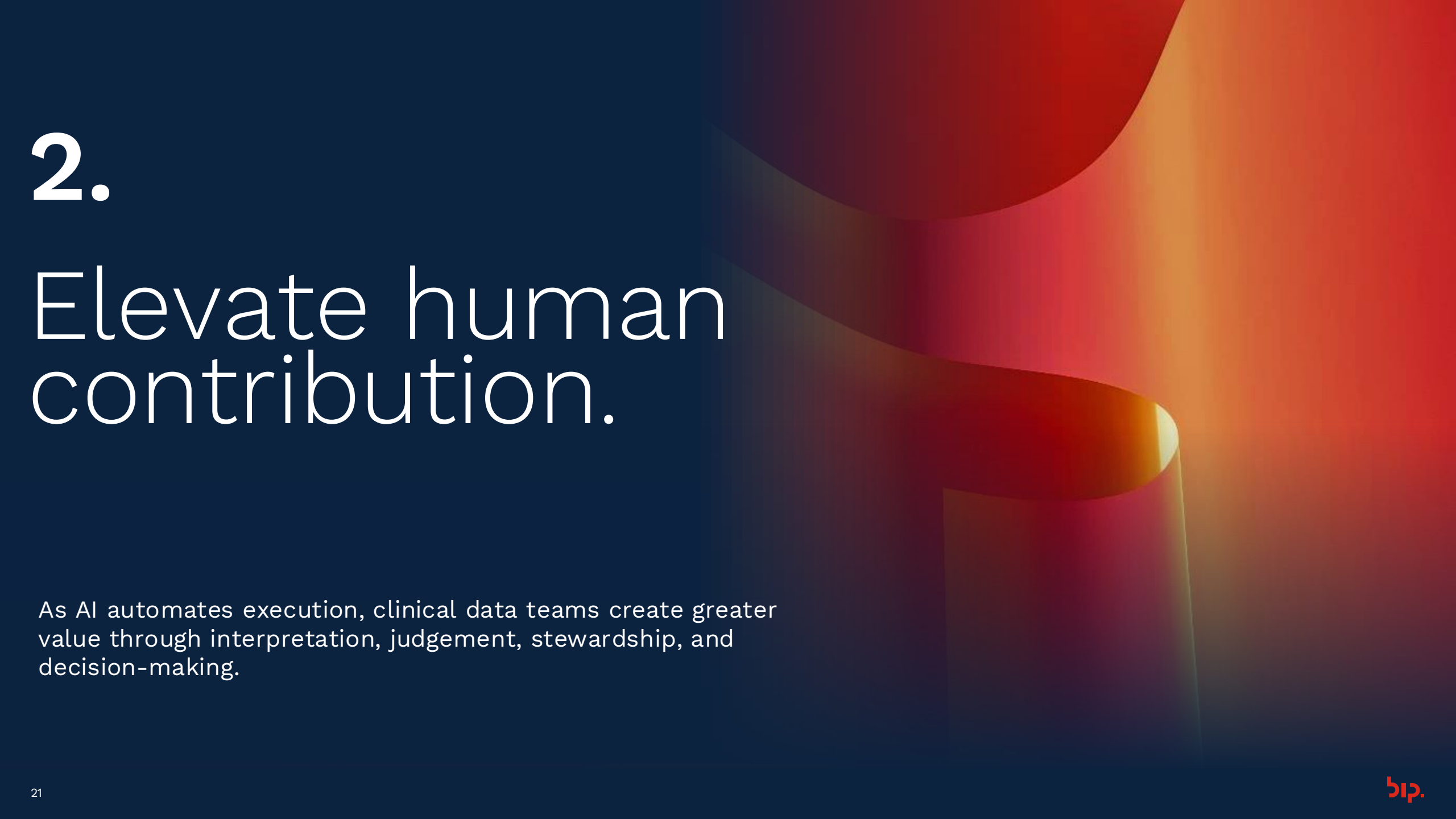
# 5 moves to turn AI adoption into long- lasting impact.

1. Start with adoption, not implementation.
2. Elevate human contribution.
3. Design governance into the workflow.
4. Measure adoption and value together.
5. Create the conditions to scale.

# 1.

# Start with adoption, not implementation.

AI value is not created when a tool is launched. It is created when people trust it, use it, and embed it into the way work gets done.



# 2.

## Elevate human contribution.

As AI automates execution, clinical data teams create greater value through interpretation, judgement, stewardship, and decision-making.

# 3.

## Design governance into the workflow.

Governance should not sit outside the work as a final checkpoint. It should be built into how AI-enabled outputs are generated, reviewed, challenged, and approved.

# 4.

## Measure adoption and value together.

Track whether teams are actually using AI-enabled ways of working, whether confidence is increasing, and whether outcomes such as speed, quality, consistency, and decision impact are improving.



# 5.

## Create the conditions to scale.

The goal is not isolated experimentation. The goal is to reach the point where AI-enabled ways of working become trusted, repeatable, and sustainable across clinical data analytics teams.







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Thank You



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