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Legacy to Leading Edge: Reinventing Biostats Programming with Technology, AI, and Agile Innovation

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Disclaimer

The opinions expressed in this presentation and on the following slides are solely those of the presenter and not necessarily those of GSK.

Agenda



Acceleration in Clinical Development



The Tipping Point



Vision for Reinvention



Technology Enablement



Automation and AI in Practice



Agile in Action



Our Success Story



Our Learning Journey



Culture as a Multiplier



Summary and Key Takeaways



Acceleration in Clinical Development

Reality Check

THEN - Traditional Development

12 – 15 Years



THEN	NOW
❖ Sequential Development	❖ Parallel Global Execution
❖ Functional Silos	❖ Cross-Functional Agility
❖ Late-Stage Programming	❖ Accelerated Programming (Dynamic and Defensive)
❖ Firefighting Mindset	❖ Continuous Readiness

NOW - Accelerated Global Development



Drug to Market – As Fast As Possible



The Tipping Point

When Speed Became Non-Negotiable

What the Traditional Model Looked Like

- Manual, repetitive programming
- Limited reuse → heavy validation burden
- Knowledge embedded in individuals
- Output generation tightly coupled to timelines
- Late-cycle changes → rework and firefighting



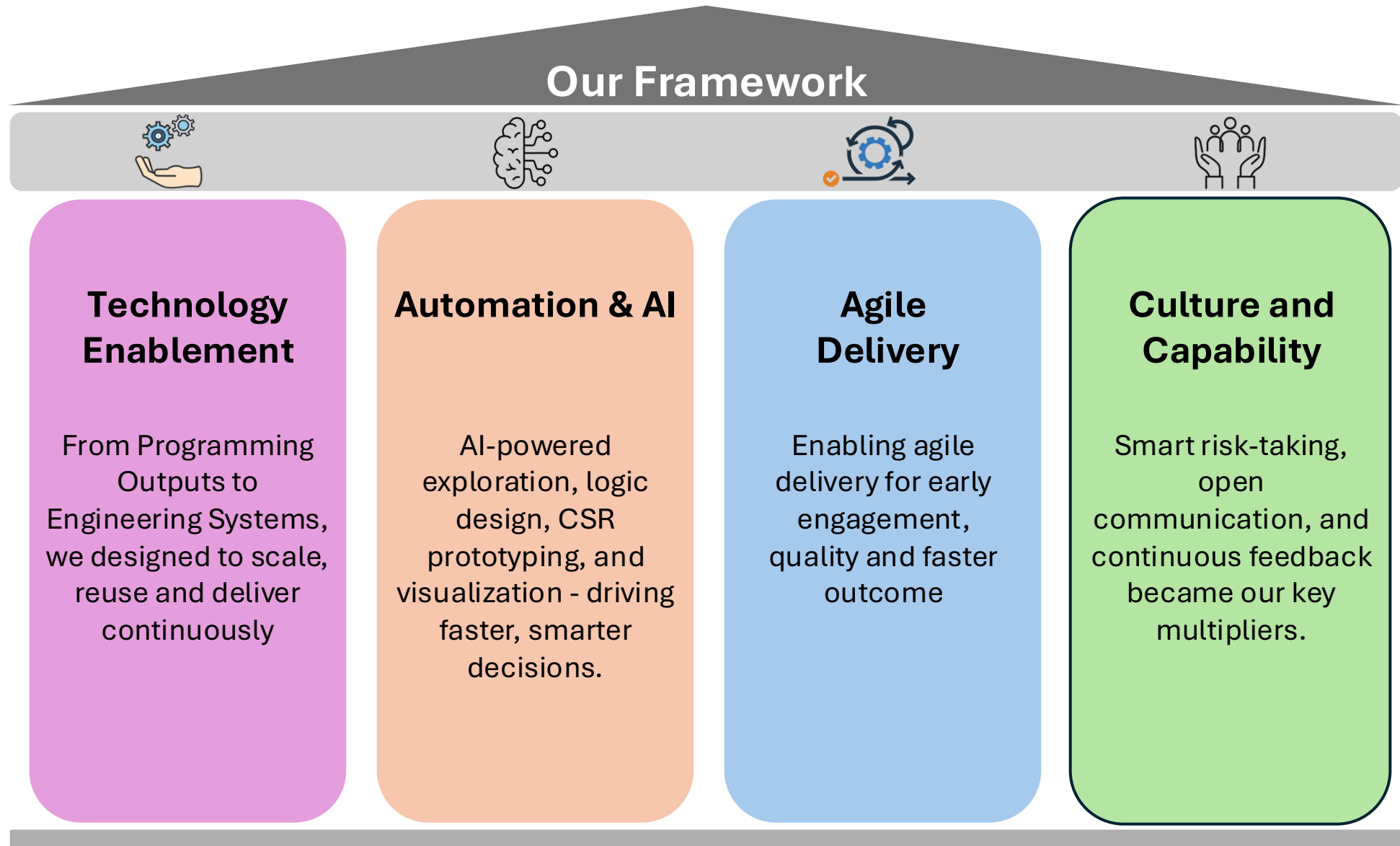
What had changed

- Acceleration and Hyper-acceleration
- Parallel multi-region submission
- Shorter decision window
- Higher demand for transparency and traceability



Vision for Reinvention

Our North Star – Agile, Scalable, Future-Ready





Technology Enablement



GitHub

Study Repo

Standard Code
Repo

Utility Repo

- Scalable, easy access
- Better integration – using multilingual coding and API calls
- Easy and controlled data access aligning to evolving policies

**This fundamentally changed
how we collaborate,
parallelize, and scale**

- Parallel component-based development
- Better version control
- Traceability
- Search and reuse



DOMINO

Data storage and
versioning

Multilingual platform
(R, SAS etc)

Seamless
Integration



Automation & AI in Practice

Practically and Responsibly



AI-Assisted Programming & Logic Design

By carefully designing prompts we developed complex, defensive and scenario driven R / SAS code, accelerating logic design; performed code translations, retaining human review and ownership



Enabled Data Review & Visualization

Built interactive shiny apps using SDTM data as source, enabling stakeholders to explore data early and independently, reducing reliance on static output and accelerate decision cycles



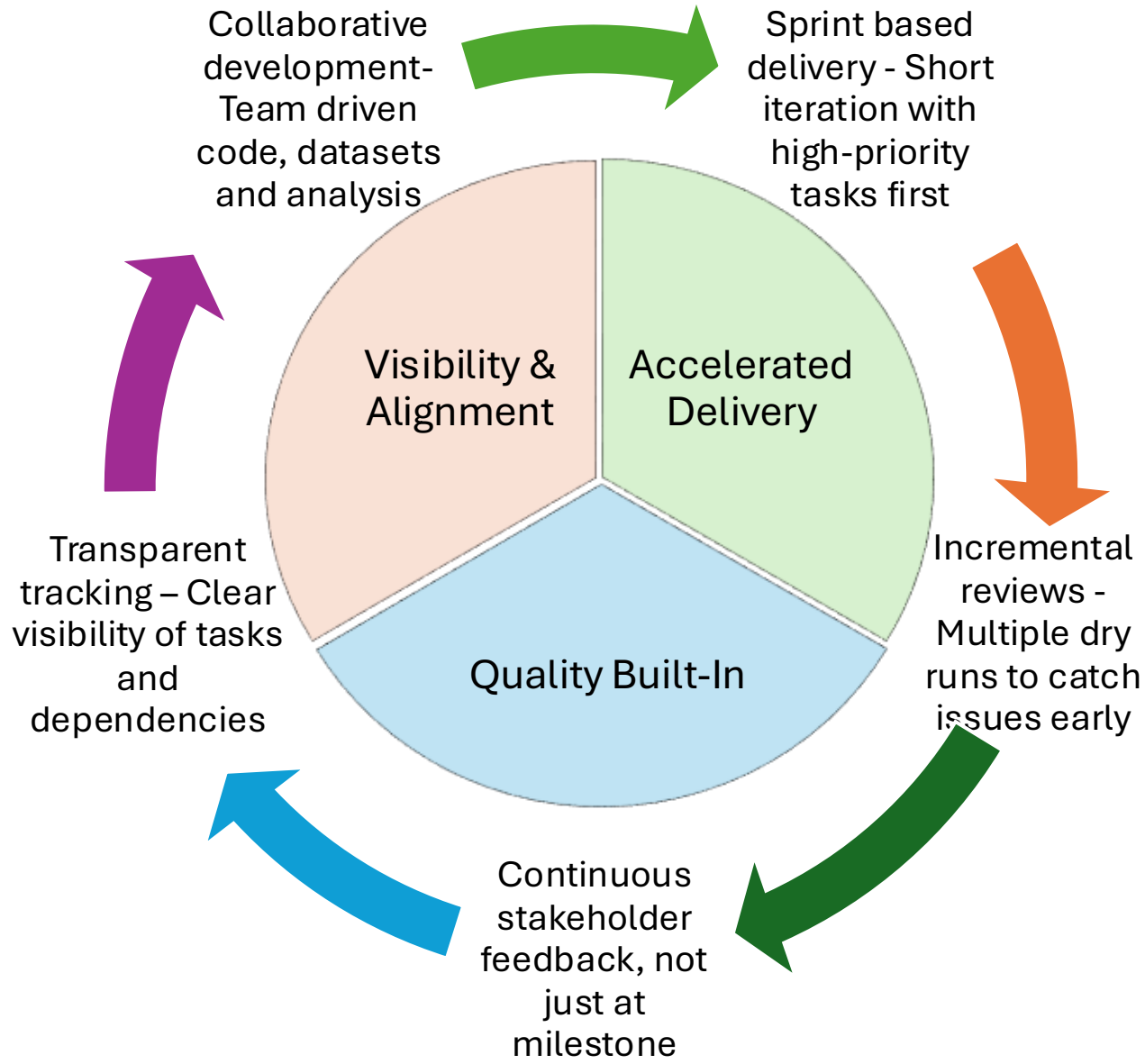
Supported Medical Writing & Insight Generation

Enabled faster CSR prototyping by providing analysis-ready data and post-analysis exploration through data visualization tool, reducing outputs and increasing insights.



Agile in Action

Turning complexity into flow



Embedding agility for speed, quality, and collaboration across the study lifecycle

- ✓ Agile delivery principles were applied at both the study team and biostatistics programming level.
- ✓ Work was planned, tracked, and reviewed iteratively, not just executed as sequential tasks.
 - ✓ Visibility & alignment: Shared backlogs and transparent tracking ensured early detection of dependencies and risks. Eliminates silo working
 - ✓ Accelerated delivery: Parallel execution, iterative sprints, risk-based QC and early integration enabled predictable, faster timelines.
 - ✓ Built-in quality: Continuous reviews, incremental testing, and reusable components ensured submission-ready outputs.



Our Success Story

What we Achieved – Accelerated Multi-Indication, Multi-Region Program

Upfront work prior to LPLV

- **6 months acceleration of recruitment** supporting parallel indication submission
- **In-stream data review** and implementation of value driven data cleaning
- **Lean Analysis Plan**, Early Dry Run conduct, **Risk based QC**, Early PK access and use data visualization tool to accelerate Biostats delivery
- **Early prototyping** of CSR using AI tools, creation of message roadmaps

Database Lock

- Accelerated DBL activities, completed in **<=2.5 weeks for pivotal studies**
- Implemented **stakeholder communication strategies**.
- **Pre-mapped resources** and pre-planned risk mitigations (**~8 months ahead**) to handle early/late data transfers and ensure seamless reconciliations.

Analysis Package Delivery

- Accelerated SAC activity in **<= 7 working days**
- Delivered **6 analysis package** for within **1.5 calendar months; 3 analysis package** (~1,000 outputs) completed in the **single week**
- Efficient **resource planning** to address overlapping activities
- Implemented **single data package** strategy for multi regional submission

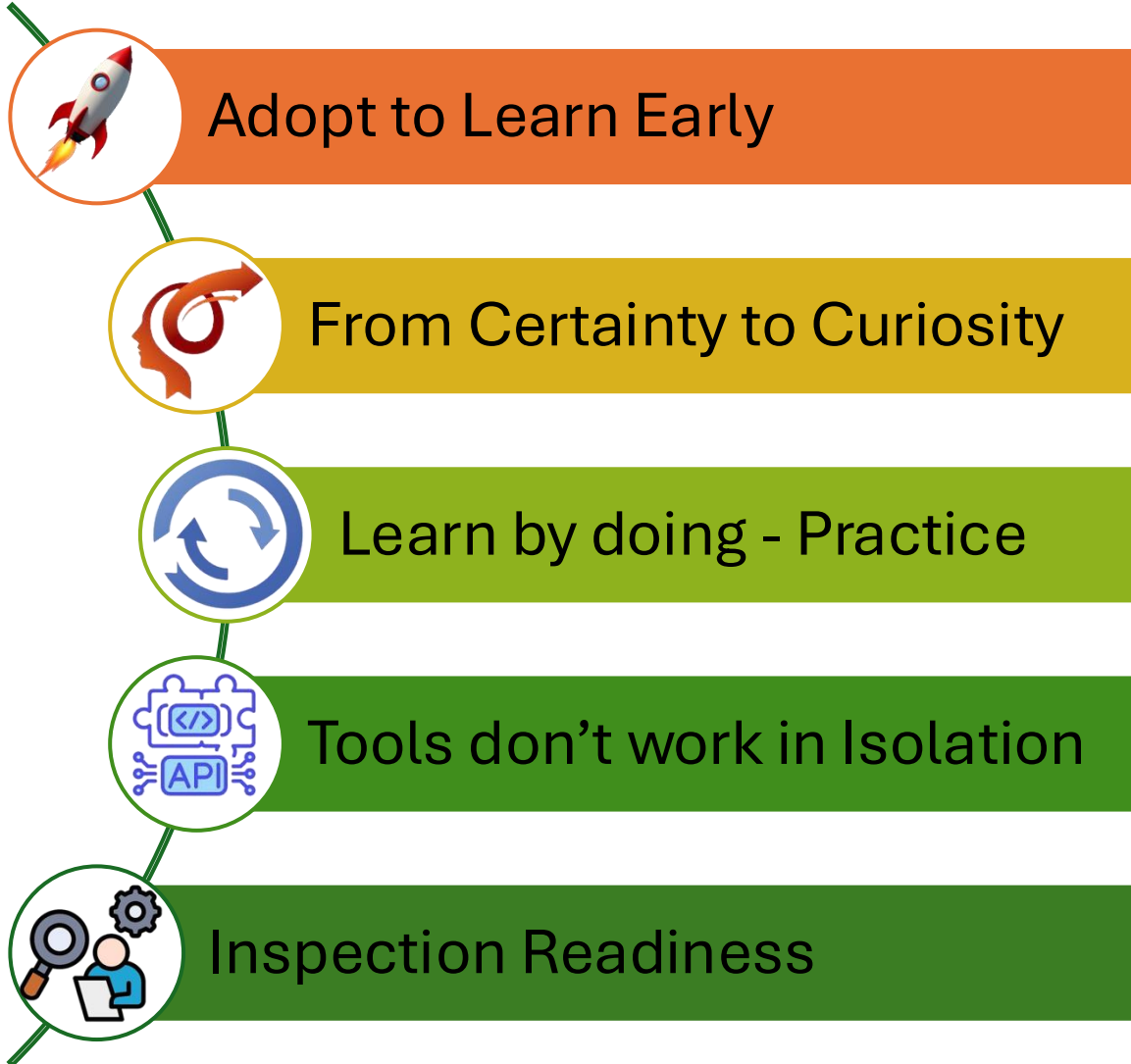
Submissions

- **Study report delivered** with in **7 weeks post analysis delivery** using AI tools.
- Post analysis delivery, **single round of review**
- **Accelerated Rest Of World submissions**, up to **~270 days earlier** filings and approvals months sooner bringing medicines to market faster while maintaining quality and safety.



Our Learning Journey

We Learned the Hard Way



- ✓ *Reinvention was not linear.*
- ✓ *Early adoption created space to experiment, learn, and adapt.*
- ✓ *The hardest shift was mindset — from certainty to experimentation.*
- ✓ *Progress came through practice: dry runs, continuous reviews, and close collaboration.*
- ✓ *System integration required strong team dialogue and deep partnership with technology.*

This learning journey enabled sustainable speed.



Culture as a Multiplier

Does Culture Matters?

Growth mindset creates Resilience. Resilience sustains change.

Resilient teams
absorbs
constant change,
stay engaged
through
uncertainty and
continue
delivering

Learn – Unlearn
– Relearn,
Iterative
learning results
in deep
compounding
knowledge

A culture of
collaborative,
clear
ownership,
rational
decision-
making, and
strategic
thinking

A growth-
oriented culture
enabled faster
adoption
without
compromising
quality

Outcomes = (Process + Technology + Tools) × Culture

Change is inevitable. Culture decides whether it breaks you or builds you.





Why this matters to Industry?

The future belongs to the most adaptive organizations

Scalable Delivery Models for Global Trials

- Enabling parallel handoff
- Reusable assets
- Platform-based, modular delivery across studies

Sustainable Speed with Compliance

- Early data readiness
- Risk-based quality
- Continuous review

Future-Ready Biostatistics Talent

- Strategic decision partners
- Technology adopters
- And leaders of integrated delivery models

This is not a blue print, its our learning journey.

- ✓ What worked
- ✓ What didn't
- ✓ What we learned delivering under real world constraints

These insights are transferable and we believe may help teams accelerate more efficiently.

THE PROBLEM



OUR VISION

THE REALITY





Summary and Closing

My Key Takeaways:

- ✓ Agility and compliance are complementary, not competing
- ✓ AI & Automation frees teams to focus on scientific judgment
- ✓ Reinvention is a continuous capability, not a one-time change
- ✓ A growth mindset turns change into progress, enabling teams to learn fast, adapt confidently, and scale impact

**Acceleration isn't about speed alone - it's about smarter decisions, made together.
Sustainable acceleration is built on intelligence, alignment, and collaboration.**

Thank You!