



Empowering Clinical Research Teams in the Age of AI

Building Resilience and Innovation in APAC

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PHUSE APAC Connect 2026 | Hyderabad | February 19–21, 2026

Acknowledgements

Bhavesh Patkar

Claude, ChatGPT, Notebook LLM, Gamma, Answerthis

**Onesto Consulting for supporting my research but all views are mine
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Today's Journey

01

The Market Reality

AI adoption acceleration, investment trends, implementation gaps. Analysis of \$9.2B market, 46% CAGR, and 500+ FDA submissions.

02

Ethics & Governance

FDA frameworks, bias mitigation, human oversight, accountability. Deep dive into January 2025 guidance and 7-step credibility framework.

03

Leadership Thinking

E.M.P.O.W.E.R. model, strategic mindset, psychological safety. How leaders must shift from expertise to learning agility.

04

Global-Local Dynamics

APAC realities, matrix management, central vs local governance. Navigating regulatory complexity and cultural factors.

05

Capability Building

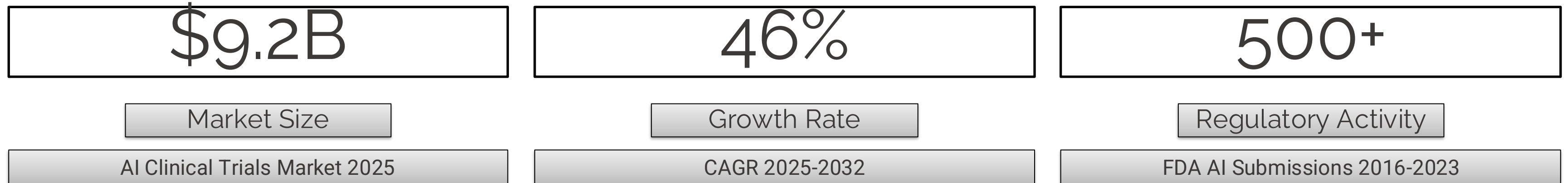
Stats & programming skills, multi-language proficiency, AI literacy. Three-year transformation journey with metrics.

06

Action Plan

Next 90 days, leadership imperatives, success metrics. Concrete steps for assess, build, pilot phases.

AI Market Explosion: 2024-2025 Data



- The AI clinical trials market reached \$9.2 billion in 2025, representing explosive growth driven by pharma's urgent need for efficiency gains and regulatory acceptance of AI-driven evidence. The compound annual growth rate of 46% through 2032 indicates this is not a passing trend but fundamental transformation of how clinical research is conducted.
- Over 500 AI/ML submissions to FDA from 2016-2023 demonstrate increasing regulatory acceptance. FDA's January 2025 guidance provides clear framework.

Industry Adoption Metrics

- 30% Rise in Pharma-Tech Partnerships - Strategic collaborations accelerating
- 18% Average Cycle Time Reduction - Proven efficiency gains
- 11% Full AI/ML Implementation - Despite investment, only 11% fully deployed

📌 **Key Insight:** While AI adoption accelerates, implementation gaps persist. The challenge is organizational readiness, not technology availability.

Why AI Transformation Fails: The Hidden Barriers

Technical Barriers

- Integration complexity with legacy systems
- Data quality issues and inconsistent standards
- Model interpretability challenges
- Infrastructure gaps

Organizational Barriers

- 67% lack confidence in AI accuracy
- Unclear governance and decision rights
- Siloed functions operating independently
- Risk-averse culture
- Budget constraints and unclear ROI

People Barriers (Most Difficult)

- Fear of job displacement
- Insufficient AI expertise
- Resistance to change
- No psychological safety
- Skills gaps at all levels

📌 **Success Pattern:** Address all three simultaneously—build technical infrastructure AND establish clear governance AND invest deeply in people transformation with psychological safety as foundation.

The Ethical Foundation: Non-Negotiable Principles



Why Ethics First?

- Protects human dignity and patient autonomy
- Prevents exploitation of vulnerable populations
- Maintains public trust in healthcare systems
- Ensures scientific integrity in research

The Five Pillars of Ethical AI

Beneficence: AI must actively promote patient welfare and improve health outcomes

Non-maleficence: First do no harm; AI systems must not cause injury through action or inaction

Justice: Fair distribution of AI benefits and risks across all populations; no systematic discrimination

Autonomy: Respect for patient and provider agency; humans maintain meaningful control

Transparency: Explainable AI with clear documentation of model logic, data sources, and limitations

Algorithmic Bias Risk: AI systems can perpetuate healthcare disparities if training data underrepresents certain demographics (race, ethnicity, gender, age, geography). Historical biases in healthcare become encoded in AI models, leading to systematically worse performance for underserved populations. This is particularly critical in APAC given population diversity.

Leadership Responsibility

- Foster ethics-first mindset throughout organization
- Stay updated with evolving ethical guidelines
- Design AI systems with transparency from day one
- Establish ethical review boards for AI deployment
- Ensure diverse representation in AI development teams

The Principle

AI augments human expertise—it never replaces human judgment. Humans must evaluate AI outputs, provide context AI cannot access, make final decisions, and take full accountability for outcomes. This is non-negotiable in regulated clinical research environments where patient safety is paramount.

When Human-in-the-Loop is Mandatory

- Patient safety decisions affecting patient welfare
- Regulatory submissions requiring qualified human review
- Protocol amendments changing study conduct
- Clinical endpoint determination requiring medical expertise
- Ethical concerns requiring human decision-making authority
- Unexpected results outside training distribution
- Novel scenarios not represented in training data

Clear Accountability Framework

01 Developers Responsible for AI model design, training, and validation documentation	02 Data Stewards Ensure data quality, representativeness, and proper governance	03 Clinical Experts Provide medical oversight, interpret outputs, validate clinical relevance
04 AI Validators Dedicated roles for systematic review of all AI outputs before use	05 Decision Makers Hold final authority and legal/regulatory accountability for outcomes	

Continuous Auditing Requirements

• Real-time performance monitoring across all AI use cases
• Regular model revalidation (minimum quarterly)
• Systematic protocols for responding to model drift
• Transparent documentation of all AI-assisted decisions
• Tracking of human override frequency and reasons

FDA's AI Credibility Assessment Framework



January 2025 FDA Guidance: Based on comprehensive analysis of 500+ AI/ML submissions received from 2016-2023. This guidance represents FDA's evolving thinking on how to evaluate AI credibility in regulatory contexts.

"Considerations for AI to Support Regulatory Decision-Making"

The 7-Step Credibility Framework

- 1 Question of Interest**
Clearly define what the AI model will address and why it's needed
- 2 Context of Use**
Specify where, when, and how the AI will be deployed in practice
- 3 Risk Assessment**
Evaluate potential harms, failure modes, and patient safety implications
- 4 Model Development**
Document training process, data sources, and design decisions
- 5 Validation**
Demonstrate performance in intended context with appropriate metrics
- 6 Monitoring Plan**
Establish ongoing surveillance protocols for production deployment
- 7 Lifecycle Management**
Plan for model updates, modifications, and version control

Key Requirements Across Framework

Data Representativeness: Training data must accurately reflect target patient populations including demographics, disease characteristics, and relevant subgroups

Bias Mitigation: Test and document model performance across demographic subgroups (age, race, ethnicity, gender, geography) to identify and address disparities

Transparency: Provide explainable model logic, decision pathways, and feature importance

Change Control: Formal protocols for model updates, version management, and revalidation triggers

Critical Implications for APAC: FDA's framework is rapidly becoming the global standard that other regulators reference. APAC organizations should proactively establish internal credibility assessment processes, train teams on framework requirements, build robust documentation infrastructure, and participate actively in regional harmonization discussions.

Global Regulatory Landscape: Key Jurisdictions

United States (FDA)

- Risk-based credibility framework approach
- Encourages innovation through iterative development
- Strong emphasis on algorithmic bias mitigation
- Pre-submission meetings encouraged for AI/ML products
- 500+ submissions analyzed inform evolving guidance

Europe (EMA)

- More structured and cautious regulatory approach
- Comprehensive upfront validation requirements
- First AI qualification opinion issued March 2025
- EU AI Act creating horizontal regulatory framework
- Emphasis on explainability and human oversight

Japan (PMDA)

- Highly sophisticated frameworks for AI-based medical devices
- Local clinical data mandatory for regulatory approval
- Strong emphasis on post-market surveillance
- Collaborative approach with industry for AI guidance

Singapore (HSA)

- Progressive regulatory sandbox programs
- Learn-as-you-go approach balancing innovation with safety
- Positioning as regional hub for Southeast Asian AI innovation
- Relatively rapid pathways compared to traditional processes

China (NMPA) & India (CDSCO)

- Rapidly evolving guidance frameworks
- Balancing innovation promotion with patient protection
- Increasing requirements for local validation data
- Growing sophistication in AI regulatory evaluation

- ❑ **The Reality for APAC Leaders:** Complex multi-jurisdictional landscape requires navigating different frameworks, timelines, and expectations simultaneously. Successful organizations build flexible compliance infrastructure adaptable to local requirements while maintaining global standards.

Algorithmic Bias: Detection and Mitigation



The Problem - How Bias Enters AI Systems

Training Data Gaps: Datasets systematically underrepresent certain demographics, ethnicities, ages, genders, or geographic regions

Historical Biases: Past healthcare disparities and discrimination become encoded in AI algorithms

Performance Disparities: Models perform poorly for underserved populations not well-represented in training

Disproportionate Impact: AI systems can worsen existing health inequities by providing inferior service to vulnerable groups

Feedback Loops: Biased predictions lead to biased interventions, which generate biased new training data

FDA Emphasis (2025 Guidance)

- Training data must reflect full diversity of intended patient populations
- Must demonstrate consistent performance across demographic subgroups statistically
- Continuous monitoring required post-deployment with quarterly reporting minimum
- Adverse impact analysis mandatory for all high-risk AI applications
- Plans for addressing identified biases must be pre-specified

Comprehensive Mitigation Strategies

- Ensure diverse demographic representation in all training and validation datasets
- Conduct performance testing across demographic subgroups (race, ethnicity, age, gender, geography)
- Implement continuous bias monitoring in production environments, not just pre-deployment
- Use established fairness metrics like demographic parity, equalized odds, and calibration
- Document known limitations and performance variations across populations clearly
- Involve diverse stakeholders in design, validation, and deployment decisions
- Schedule periodic bias audits by independent teams not involved in development

Critical APAC-Specific Implications: Asian populations frequently underrepresented in Western training datasets historically. Genetic, lifestyle, and environmental differences affect AI model performance significantly. Local validation studies essential before deployment in APAC markets.

Essential Governance Components

Clear Decision Rights Explicitly define who approves AI use cases, vendor selections, and implementations	Risk Categorization Tiered approach based on patient safety impact (high/medium/low risk tiers)	Escalation Pathways Clear protocols for when and how to escalate concerns about AI performance
Validation Standards Minimum acceptance criteria for AI tools before deployment	Monitoring Cadence Frequency of performance reviews appropriate to risk level	Version Control Formal processes for managing AI model updates and changes
Incident Response Documented protocols for addressing AI failures or unexpected behaviors		

Critical Cross-Functional Collaboration

Break down organizational silos between: Biostatistics, Data Management, Medical Writing, IT/Technology, Clinical Operations, Quality Assurance, and Regulatory Affairs.

AI Validators as Core Organizational Function

Establish dedicated roles with clear responsibilities for systematic review of all AI outputs before use in decisions or submissions, edge case identification, performance tracking, feedback loops to development teams, and maintaining comprehensive audit trails.

Common Governance Failures to Avoid

- Unclear override authority (who can reject AI recommendations and when?)
- No systematic review process or inconsistent application
- Treating all AI applications with same risk level (one-size-fits-all)
- Reactive rather than proactive monitoring approaches
- Inadequate documentation of AI-assisted decisions and rationale
- Governance policies that exist on paper but aren't followed in practice

How Leaders Must Think Differently



The Transformation Imperative

70%

Leadership Impact

Of employee engagement determined by leadership quality

202%

Performance Gain

Higher performance by empowered leaders

Traditional command-and-control fails in AI era. Leaders must shift from knowing answers to enabling discovery.

Critical Mindset Shifts

- 1

From Expertise → Learning Agility
Leaders must be voracious learners
- 2

From Control → Enablement
Remove barriers, don't dictate solutions
- 3

From Stability → Adaptability
Embrace constant change
- 4

From Individual → Collective Intelligence
Leverage team capabilities

Psychological Safety Non-Negotiable

Teams need permission to:

- Experiment without fear of failure
- Question AI outputs openly
- Admit gaps without losing credibility
- Challenge processes and propose alternatives
- Share failures for organizational learning

Without Safety: AI adoption stalls, innovation dies, talent leaves

The E.M.P.O.W.E.R. Leadership Framework

E - Envision Possibilities

Map AI to business strategy—
transformation not pilots

M - Master Self-Awareness

Assess team AI readiness through
structured analysis

P - Prioritize Data-Informed Decisions

Use evidence, not intuition, for AI
investments

O - Optimize Team Composition

Build diverse skills: technical, clinical,
regulatory

W - Welcome Experimentation

Create safe space for intelligent failures

E - Embed Continuous Learning

Invest in training, certifications, knowledge
sharing

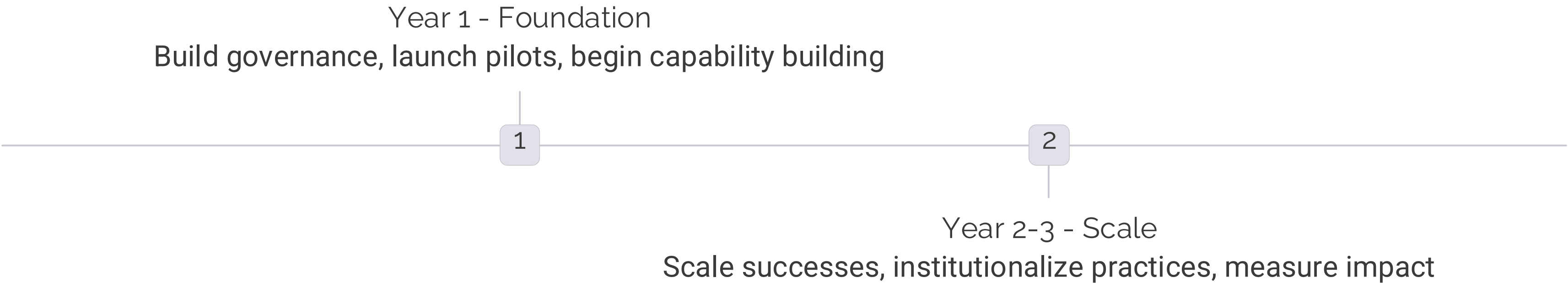
R - Recognize & Reward Progress

Celebrate milestones, skill development, innovation

Practical Applications

Envision	3-year AI roadmap linked to business goals
Master	Team capability assessments every 6 months
Prioritize	ROI analysis for each AI use case
Optimize	Cross-functional AI task forces
Welcome	Monthly innovation showcases, failure awards
Embed	Quarterly certification tracking
Recognize	AI Champion awards, career advancement

Phased Implementation



Strategic Vision

- Connect AI to business outcomes
- Communicate transformation narrative
- Balance short/long-term goals

Change Management

- Address resistance proactively
- Build champion coalitions
- Create psychological safety
- Navigate organizational politics

Technical Fluency

- Understand AI capabilities/limitations
- Ask informed questions
- Make risk-based decisions
- Distinguish hype from reality

Ethical Stewardship

- Champion responsible AI
- Monitor algorithmic bias
- Ensure human oversight
- Maintain transparency

Data-Driven Decision Making

- Demand rigorous metrics
- Use evidence to challenge assumptions
- Track leading/lagging indicators

Collaboration & Influence

- Work across organizational silos
- Influence without authority
- Build stakeholder trust
- Navigate matrix management

Building an AI-Ready Culture

Core Cultural Elements

Growth Mindset

Embrace learning, value experimentation, celebrate intelligent failures

Collaboration

Break silos, cross-functional teams, share knowledge openly

Data-Driven

Base decisions on evidence, challenge with data, invest in data literacy

Experimentation

View pilots as learning experiments, rapid iteration, fail fast/learn faster

Cultural Indicators

- Leaders visibly use AI tools
- Questions welcomed, not punished
- Time allocated for learning
- Failures discussed openly
- Innovation recognized in reviews
- Cross-functional collaboration encouraged
- Data-driven arguments win
- Rapid iteration preferred

❏ **Leadership Role:** Culture built through daily actions, not mission statements

Leadership Measurement: What Gets Tracked Gets Done

Business Metrics

Cycle time reduction	15-20% Year 1
Quality defects	-25%
Voluntary attrition	-15% by Year 3
Employee engagement	+35% by Year 3
AI adoption rate	70% using tools regularly

Capability Metrics

- Skills completion: 95% by Year 3
- Multi-language programmers: 60% SAS + R/Python
- AI literacy: 100% completion mandatory
- External certifications tracked

Culture Metrics

- Psychological safety scores (quarterly surveys)
- Learning culture participation
- Innovation rate (experiments launched/scaled)
- Cross-functional collaboration effectiveness
- Leadership effectiveness (360° feedback)

Dashboard Principles

Combine leading + lagging indicators, make metrics actionable and transparent, review regularly in leadership meetings, tie to performance incentives

APAC Reality: Matrix Management Complexity



APAC Operating Model

- Matrix structures with functional reporting to global heads (US/Europe)
- Regional oversight for local operations and compliance
- Project allocation decisions by global teams

Tension Points

Decision Authority Who decides on AI tool selection?	Budget Control Global vs regional spending authority	Standards Alignment Global SOPs vs local regulatory requirements
Talent Development Competing priorities for limited resources	Communication Timing US daytime = APAC nighttime challenges	

AI Governance Complexity

Central teams decide: platforms, vendors, models (global standards)

APAC teams face: local regulatory interpretation, workforce skill gaps, data localization requirements, cultural adaptation factors

Success Patterns

- Clear decision rights documented in RACI matrices
- Regional adaptation frameworks with defined boundaries
- Bidirectional communication channels (global ↔ local)
- Dedicated liaison roles bridging global and regional
- Regular forums connecting stakeholders across regions

APAC-Specific Implementation Challenges



Regulatory Heterogeneity

Japan	Sophisticated but highly specific requirements
China	Evolving and sometimes inconsistent guidance
India	Balancing innovation with practical constraints
Singapore	Progressive but represents small market
Australia	Well-harmonized with international standards

Resource Constraints

- Talent concentration in major tech hubs vs distributed sites
- Limited local AI/ML expertise availability
- Infrastructure gaps in emerging economy locations
- APAC often lower priority for global AI investment

Data Localization Requirements

- **China:** Strict data sovereignty and residency laws
- **India:** Evolving data protection framework
- **Singapore:** Generally permissive with proper governance
- **Implication:** Centralized AI models may not deploy across all markets

Cultural Factors

- Varying attitudes toward AI and automation
- Different decision-making processes and hierarchies
- Communication styles (direct vs indirect)
- Risk tolerance levels vary significantly
- Face-saving considerations in failure discussions

Bridging Global and Local: Effective Governance



Governance Model Options

Centralized Global standards applied uniformly Pros: Consistency, efficiency, easier compliance tracking Cons: May not address local nuances, slower adaptation	Federated Regional autonomy with alignment frameworks Pros: Local flexibility, faster response to regional needs Cons: Potential inconsistency, complexity in coordination	Hybrid (Recommended) Global principles with local implementation flexibility Pros: Balance of consistency and adaptability Cons: Requires clear boundaries and strong communication
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Decision Matrix - Define Who Decides What

Global Level	Platform selection, vendor contracts, core training programs
Regional Level	Local regulatory adaptations, regional vendor relationships
Local Level	Implementation details, country-specific compliance

Communication Protocols

- Regular global-regional-local forums (monthly minimum)
- Clear escalation pathways for decision conflicts
- Feedback mechanisms from local to global
- Standardized documentation for transparency

Success Factors

- Clear delegation of authority with documented RACI
- Respect for local expertise and context
- Balanced decision-making (not always global wins)
- Investment in dedicated liaison roles

APAC Leadership Imperatives

1 Navigate Matrix Complexity

- Build strong relationships with global functional leaders
- Clarify decision rights proactively before conflicts arise
- Communicate local realities effectively to global teams
- Master influence without direct authority

2 Adapt Global to Local Context

- Translate global AI strategies to local implementation
- Address cultural factors in change management approaches
- Ensure regulatory compliance for each country
- Customize communications for local audiences

3 Build Regional Capability

- Invest in local talent development programs
- Create APAC-specific knowledge networks
- Share best practices across countries in region
- Develop regional centers of excellence

4 Advocate for APAC Voice

- Ensure APAC perspectives heard in global decisions
- Demonstrate clear ROI of regional investments
- Propose APAC-relevant pilot programs
- Build case studies showing regional success
- Participate actively in global strategy discussions

Storytelling with Data (Mandatory)

- Communicate insights compellingly using visualizations
- Build narratives around data to influence decisions
- Provide context that makes numbers meaningful
- Essential for all roles to effectively influence and persuade

Agile/Scrum Ways of Working (Mandatory)

- Iterative development cycles and sprints
- Sprint planning and retrospectives
- Enables rapid AI experimentation and learning
- Adaptive planning based on feedback

AI Awareness Training (100% Mandatory)

- What AI is and isn't capable of doing
- Applications in clinical development workflow
- Limitations and risks of AI systems
- Responsible use policies and guidelines
- Regulatory considerations for AI in pharma

Prompt Engineering for LLMs (Mandatory)

- Crafting effective prompts for language models
- Iterative prompt refinement techniques
- Output verification and quality checking
- Use cases by function: coding assistance, writing support, data analysis, document review
- Best practices for different AI tools

Statistics for Programmers

Understand methods being implemented in code
Descriptive and inferential statistics fundamentals
Common clinical analyses: t-tests, ANOVA, Kaplan-Meier, Cox regression
Reading and interpreting Statistical Analysis Plans (SAPs)
TLF development understanding

Data Science for Data Managers

Transition from data custodian to analyst role
Exploratory data analysis techniques
SQL and database fundamentals
Python/R basics for automation
Machine learning literacy
Data quality automation tools

Programming for Statisticians

- R/Python for modern statistical practice
- tidyverse ecosystem for data manipulation
- Data wrangling and transformation
- TLF production with pharmaverse packages
- Version control with Git/GitHub

Advanced AI for Select Staff

- RAG (Retrieval-Augmented Generation) architectures
- Fine-tuning LLMs for specific use cases
- MLOps for production AI deployment
- For senior technical staff building AI solutions

❏ **R and Python Multi-Language Upskilling:** Multi-language capability increasingly expected in industry. FDA/EMA accept R/Python for regulatory submissions. Target: 60% of programmers multi-language proficient by Year 3

Three-Year Capability Transformation Journey



Year 1 - Foundation (Months 1-12)

Universal training rollout: AI awareness for 100%, prompt engineering for all
Statistics for Programmers course launch
Inaugural intern cohort recruitment
Launch 3-5 AI pilot projects across functions
70% skills completion target
Establish baseline metrics for tracking progress

Year 3 - Institutionalize (Months 25-36)

Capability embedded in performance management system
Career progression explicitly tied to capability growth
Company recognized as talent development destination
Targets: 95% skills completion, 60% multi-language, -15% voluntary attrition
AI capabilities fully integrated into all workflows



Year 2 - Scale (Months 13-24)

Full enrollment across all technical tracks
External certifications partnership: PSI, PHUSE programs
3 intern cohorts per year established
Thought leadership: Internal experts present at conferences
Target: 25% of programmers multi-language capable
Scale successful pilots to production

Key Success Metrics Throughout

- Track completion rates by individual and team
- Monitor certifications earned
- Measure employee engagement scores
- Client feedback on quality improvements
- Voluntary attrition reduction tracking

Build Internal Capability When:

- Core competency critical to competitive differentiation
- Long-term strategic capability needed (5+ years)
- Highly sensitive IP or proprietary methods involved
- High control requirement for quality/compliance
- Sufficient scale to justify investment in training
- Talent retention strategy for key staff

Partner/Outsource When:

- Non-core activities (routine, repeatable tasks)
- Need for highly specialized niche expertise
- Resource constraints limit internal capacity
- Want to accelerate time-to-value rapidly
- Access to cutting-edge AI tools through vendor
- 70% of companies cite AI/ML capability as key outsourcing driver

Strategic Outsourcing Reality in Pharma

- 25-75% of SDTM/ADaM creation now outsourced across industry
- Comparable outsourcing levels for TLF programming
- Shift from cost-based to capability-based vendor selection
- CROs investing heavily in AI capabilities

Recommended Hybrid Approach

Build Core Internal: AI validators and governance roles, prompt engineering experts, AI integration architects

Partner for: Specialized AI tool access and licenses, surge capacity for peak demands, niche technical expertise

Measuring Capability Building Success

Participation Metrics

- Training enrollment rates by function/level
- Completion rates by track and timeframe
- Time to complete programs (track velocity)
- Certification acquisition rates
- Voluntary participation in optional programs

Competency Metrics

- Skills assessments: pre-training and post-training
- Multi-language proficiency testing
- AI tool adoption and usage rates
- Quality of work outputs (defect rates)
- Code review scores for programmers

Business Impact Metrics

- Cycle time improvements in processes
- Quality defect reduction percentages
- Employee engagement survey scores
- Voluntary attrition rates by function
- Client satisfaction improvements

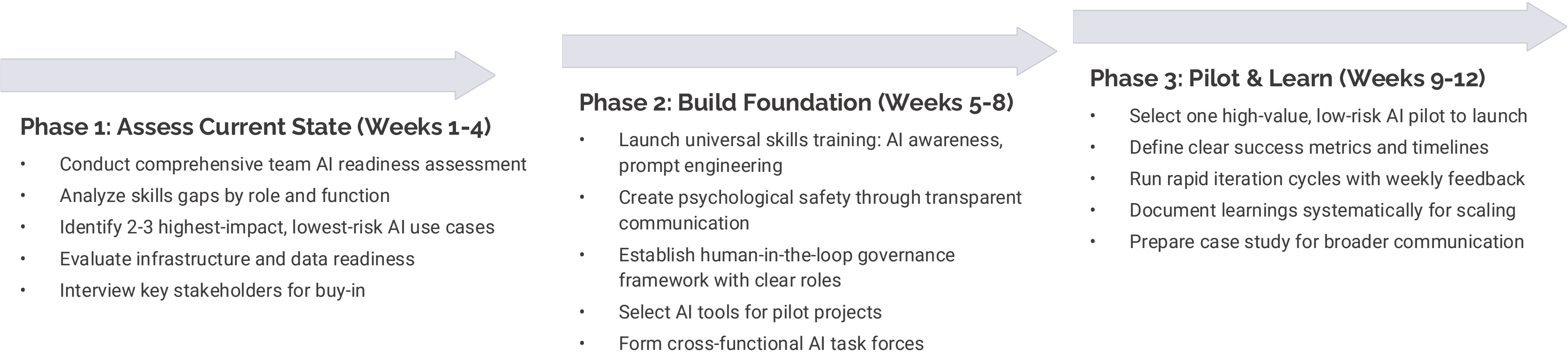
Return on Investment

- Cost per training hour delivered
- Productivity gains per employee
- Client satisfaction score improvements
- Talent acquisition advantages (employer brand strength)
- Retention ROI: Cost of replacement vs training investment

Leading Indicators

- Learning culture indicators (informal knowledge sharing)
- Manager engagement in team development
- Employee Net Promoter Score for development programs
- Internal mobility and promotion rates

Action Plan: Your Next 90 Days



Critical Leadership Actions Throughout

Communicate transformation vision weekly in team meetings
Actively remove barriers to experimentation
Visibly model learning behaviors (use AI tools yourself)
Celebrate smart failures publicly
Provide air cover for teams taking calculated risks

Week 13: Review, Reflect, Scale

Conduct retrospective on 90-day journey, scale successful approaches, adjust course based on learnings, plan next 90-day cycle.

Five Principles to Remember

1 Ethics First

Every AI decision must be grounded in ethical principles. Patient safety, data privacy, and bias mitigation are non-negotiable foundations.

2 Human-AI Partnership

AI augments human expertise—it never replaces human judgment. Always maintain meaningful human control, especially in high-stakes decisions affecting patients.

3 Capability is Competitive Advantage

Invest deliberately and systematically in people development. Companies that develop their talent consistently outcompete those that don't.

4 Leadership Model Matters

E.M.P.O.W.E.R. framework guides effective transformation. Build psychological safety, make data-informed decisions and optimize team composition.

5 APAC Context is Unique

One-size-fits-all approaches fail. Success requires culturally-sensitive, locally-adapted implementation that respects regional differences.

Resources and References

Key Regulatory References

- FDA (2025): "Considerations for AI to Support Regulatory Decision-Making"
- EMA AI Qualification Opinion (March 2025)
- ICH E9(R1) Addendum on Estimands

Recommended Reading

- "AI in Clinical Development" - PHUSE White Paper Series
- "Machine Learning in Drug Development" - Nature Reviews
- "Ethical AI in Healthcare" - WHO Guidelines

Professional Organizations

- PHUSE (Pharmaceutical Users Software Exchange)
- PSI (Statisticians in the Pharmaceutical Industry)
- DIA (Drug Information Association)
- ASA Biopharmaceutical Section

Training Resources

- PHUSE Training Portal
- PSI Certificate Programs
- Coursera: AI for Medicine Specialization
- edX: Clinical Data Science

Consulting & Advisory

Onesto Consulting: AI transformation strategy

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Key Takeaways for APAC Leaders



Regional Context Matters

- APAC faces unique challenges: matrix complexity, regulatory diversity, resource constraints
- Success requires balancing global standards with local adaptation
- Build strong regional capabilities while leveraging global resources

People are the Bottleneck, Not Technology

- Technical barriers are solvable with investment
- People transformation is hardest but most critical
- 70% of engagement depends on leadership quality
- Invest heavily in capability building and psychological safety

Ethics and Governance are Foundations

- Cannot be afterthoughts or compliance checkboxes
- Must be embedded from day one in all AI initiatives
- Human-in-the-loop principle is non-negotiable
- Transparency builds trust with patients and regulators

Take Action Now

- Start with 90-day action plan: Assess, Build, Pilot
- Don't wait for perfect conditions—begin learning
- Focus on high-value, low-risk use cases first
- Document and share learnings across organization

Collaboration is Key

- Break down organizational silos actively
- Build regional APAC networks for knowledge sharing
- Partner with vendors strategically for capability access
- Engage with regulators early and often

Building the Future Together

"In an industry where talent is the scarcest resource, a company's ability to develop people becomes its most durable competitive advantage."

Let's empower our teams to lead APAC's clinical research transformation

Ashwini Mathur

Executive Director, Onesto Consulting

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Questions & Discussion