



Building Quality Culture and Capabilities

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IPA CONFERENCE | FEBRUARY 2019

- 1 Quality culture matters: Increasingly companies believe that culture matters; this is also reflected in their efforts to work on it!!



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Do You Have a Quality Culture?

Perspectives on the value of creation and assessment of quality culture

By David Keeling, Paul Rutten and Vanya Telpis, McKinsey & Company

Oct 17, 2017

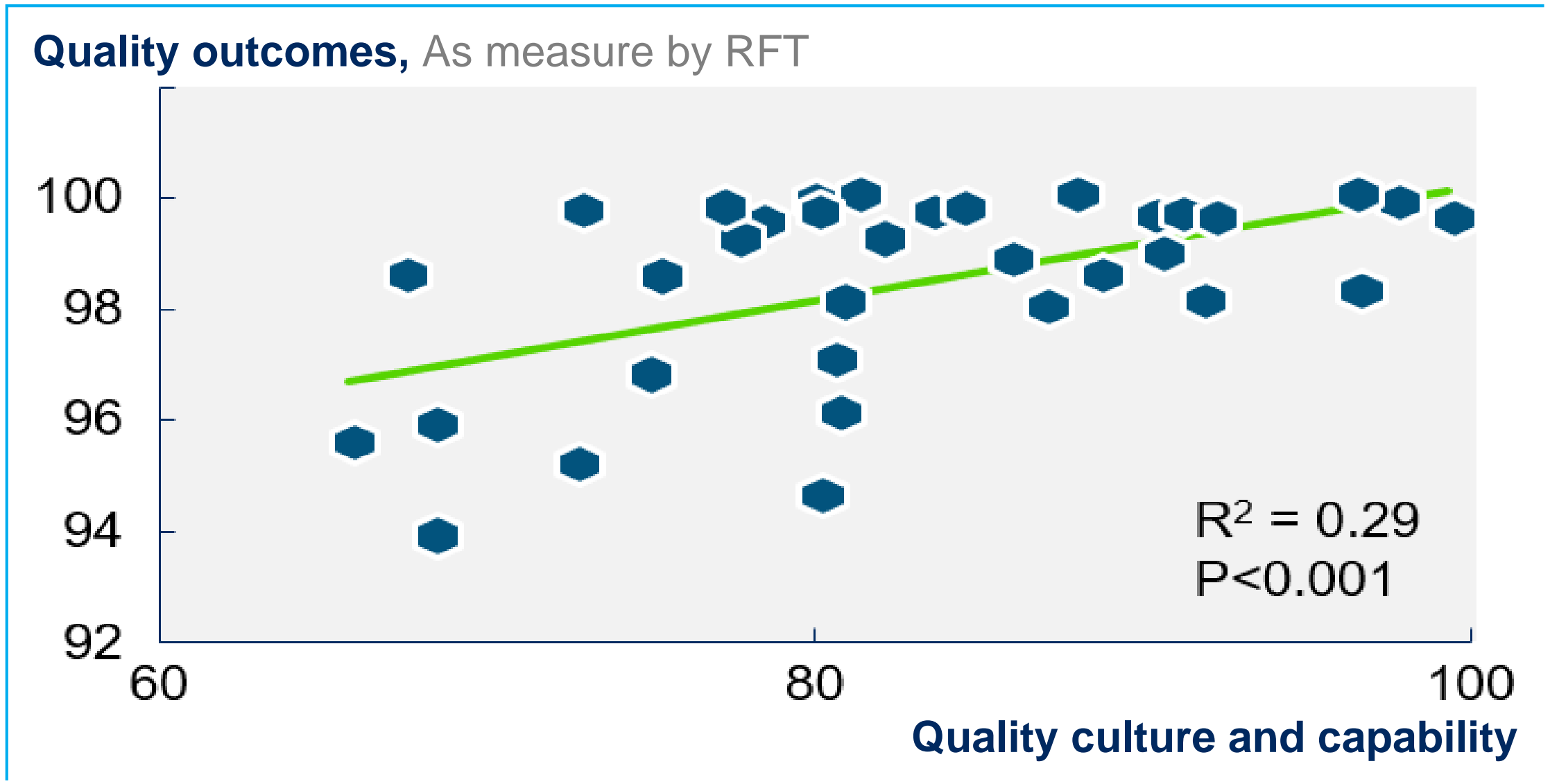
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Measuring quality culture is essential to improving mindsets and behaviors in pharma companies. The challenges to measuring culture are significant, but our research demonstrates that they can be overcome. While there is no ultimate metric for culture, good measures are available, each with proven correlation to quality outcomes. Indeed, companies with a strong quality culture are distinguished by their ability to measure culture and apply those insights to culture improvement efforts.

1 Data supports: Quality outcomes are strongly correlated with quality culture



2 What is quality culture: Five (5) pillars of strong quality culture

Quality performance is communicated clearly, regularly monitored and reinforced through robust metrics, governance and incentives

**Quality
as top priority**

All employees especially “shop floor” ones understand and follow the SOPs/ guidelines even when “no one is watching”

**Employees
own quality**

Managers spend time on the shop floor to observe operations (“gemba”), effectively identify quality improvements, coach employees and reinforce the importance of quality

**Leadership
role
models**

Employees are not afraid to raise quality issues and proactively flag continuous improvement opportunities, whereupon leaders listen and act appropriately

**Open
dialogue**

**True
resolution
of problems**

Teams carry out rigorous, high-quality investigations to identify the right root cause and preventive actions and drive solutions to avoid recurrence of issues

3 Culture can be measured reasonably well!!

Combination of measures



Quality culture survey (on annual basis) to measure intangible culture elements

- 5 elements
 - Leadership
 - Governance
 - Capabilities
 - Integrity
 - Mindset
- Monthly/ quarterly pulse check survey to measure progress on 5 elements

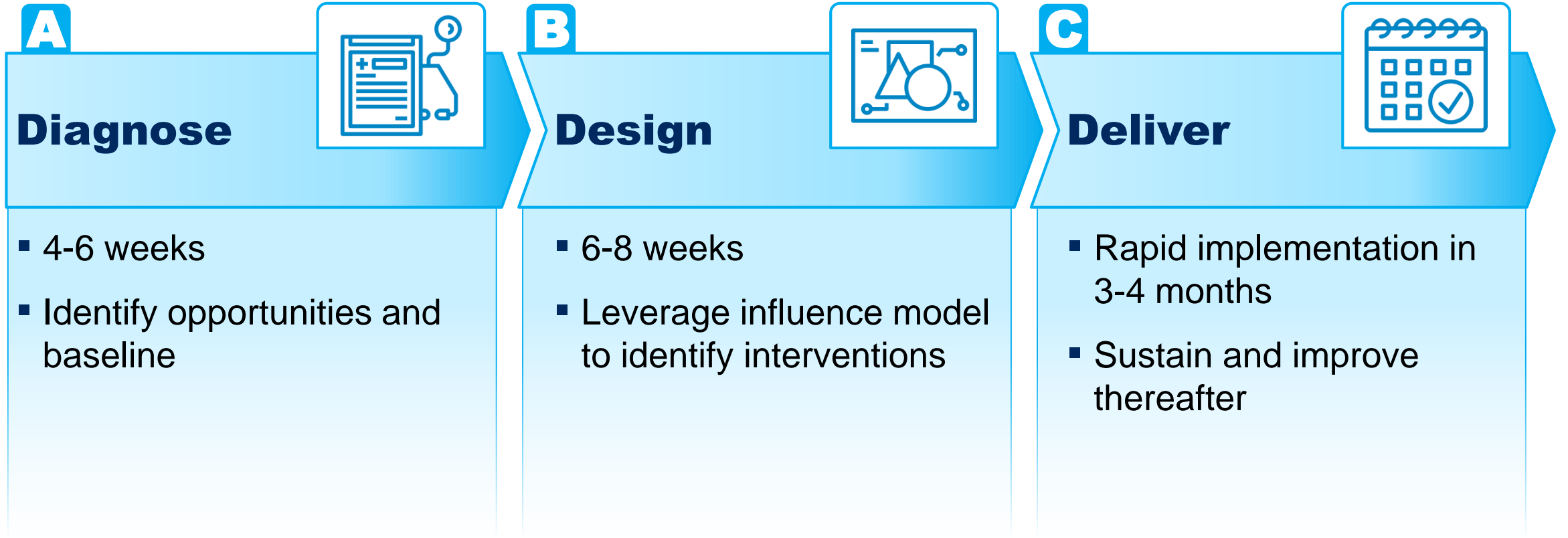
Tangible culture indicators

- CAPAs with preventive measures
- Planned maintenance rate
- Employee turnover rate
- Human error deviations
- Deviations w/o assigned root cause
- CAPA effectiveness (retraining)
- Recurring deviations

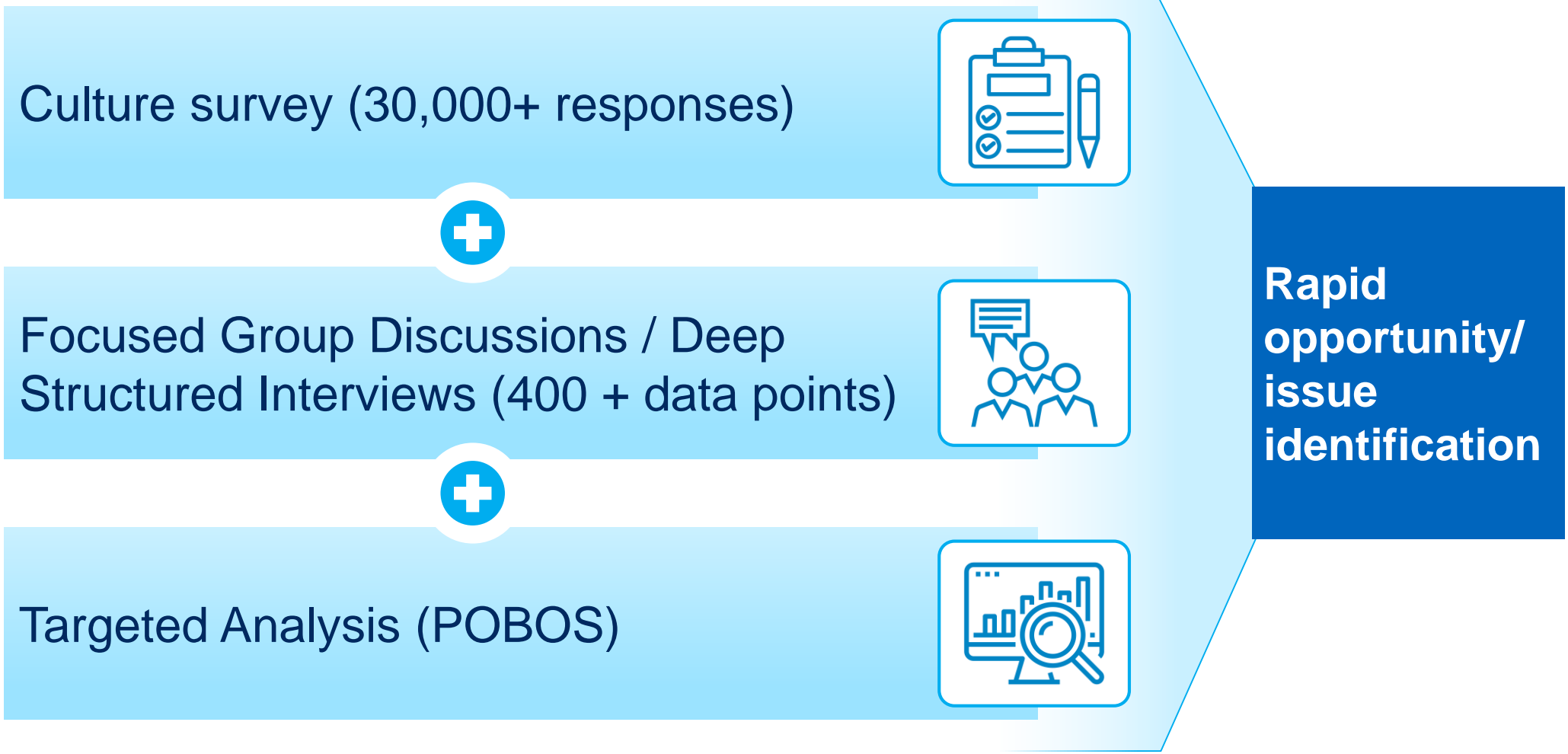
4 You can build quality culture: You don't need a lifetime – shift in culture can be demonstrated in 4-6 months!!



5 How: Three steps to build quality culture



A Use a combination of survey, practices, tools and data



A Common observations from firms that have challenging quality culture

- 1** Leadership's lack of understanding and denial – failure to acknowledge that problems exist and a false sense of self – “we know-it-all”
- 2** Failure to consistently demonstrate “Quality first behavior” in decisions and actions (not just talk) – “implicit delivery focus”
- 3** There has been progress but systems for raising quality issues and identifying continuous improvement opportunities remain inadequate
- 4** Gaps between practice and procedure at Shop/ lab floor – “Tick the box mindset”
- 5** Gaps in Investigation – Unable to identify root cause of issues and put in place robust CAPAs
- 6** Limited understanding of metrics with ineffective governance
- 7** Weak planning system and limited cross functional collaboration
- 8** Training ≠ Capability building

B Culture transformation model – “Influence model”

4-part culture-transformation framework

“I will change my behavior if...”

Fostering true understanding and conviction

- “- I know what is expected of me – I agree with it, and it is meaningful”
- “- I am committed to change and action”

Reinforcing with formal mechanisms

- “- new ways of working are reinforced through structures, processes and systems, communication and rewards”

Culture transformation

Role-modeling

- “- I see superiors, peers and subordinates behaving in the new way”

Developing talent and skills

- “- I, (both existing and new employees), have the skills and competencies to behave in the new way”

B Illustrative actions from successful case examples

4-part culture-transformation framework

“I will change my behavior if...”

Fostering true understanding and conviction

- Openness and change **leadership program**
- Multi channel, 2-way communication
- Formal platforms to raise issues

Role-modeling

- Gemba - Senior leaders role modeling quality in day-to-day behaviors
- Symbolic acts by leadership team that further establish importance of quality

Culture transformation

Reinforcing with formal mechanisms

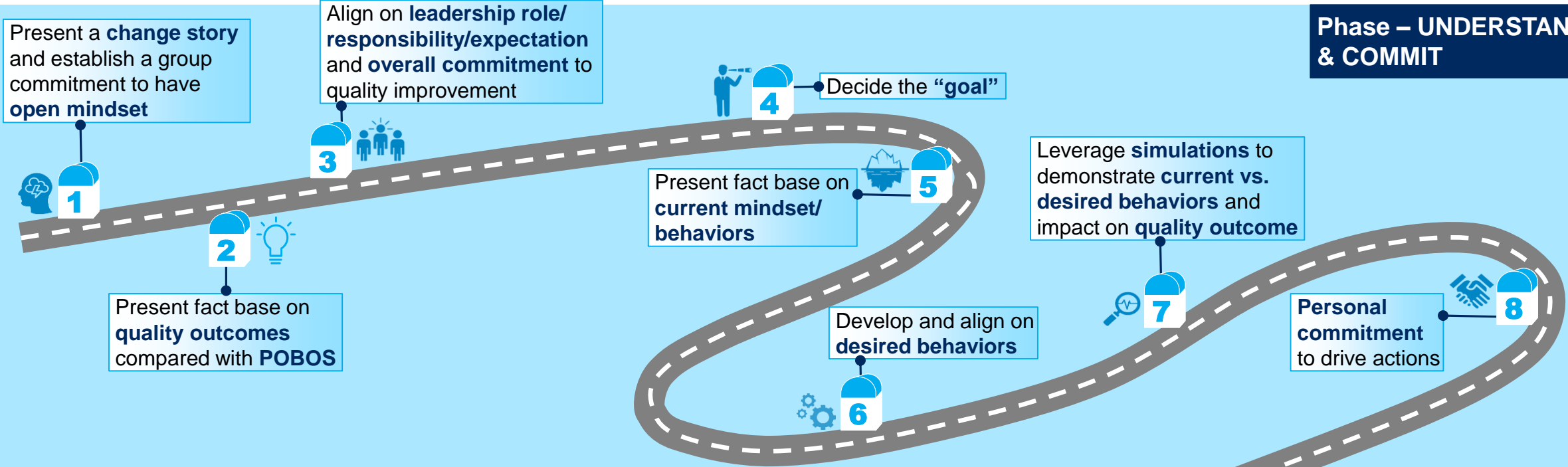
- Effective quality governance - right metrics, robust governance processes including notification to management
- **Rewards & Recognition** to encourage good quality outcomes

Developing talent and skills

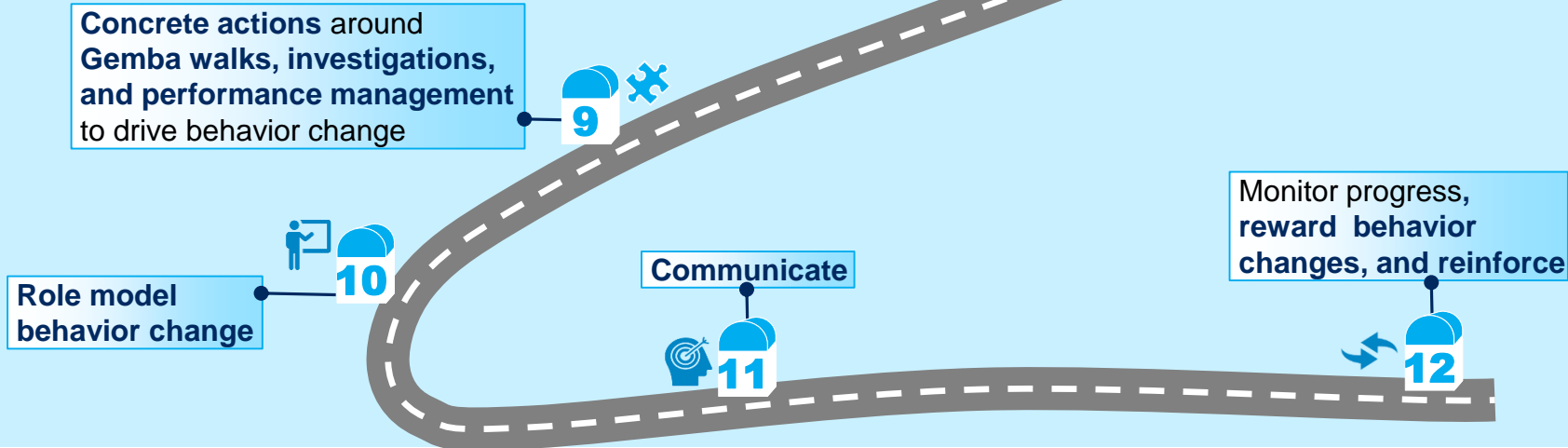
- Technical, managerial & behavior skills across levels (e.g., Investigation capabilities)
- **Digital & analytics** for quality improvement & capability building

Leadership change journey

Phase – UNDERSTAND & COMMIT



Phase – IMPLEMENT & REINFORCE



True capability building goes far beyond traditional 2-3 day class room training

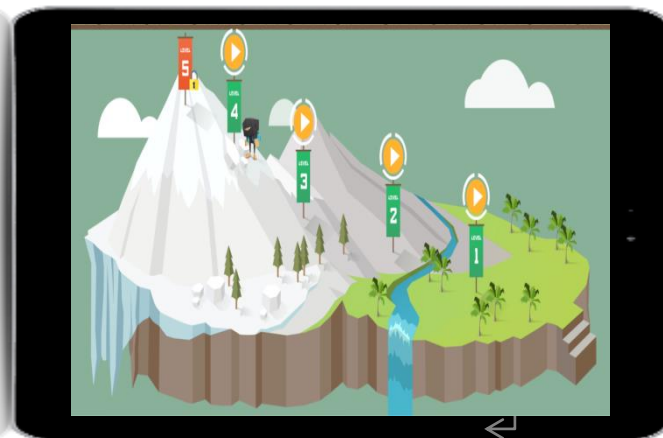
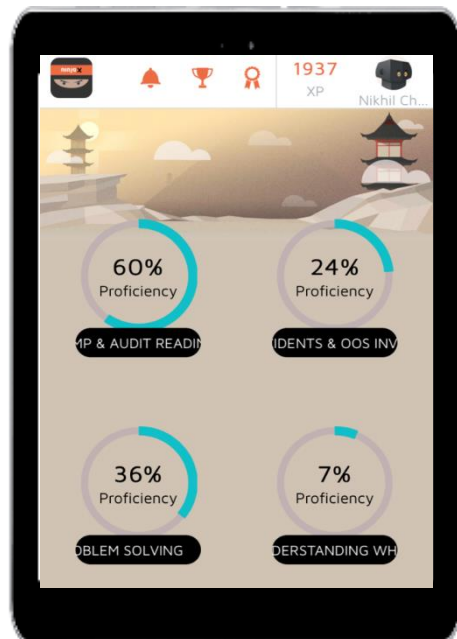
Traditional 'training'



Building 'capabilities'

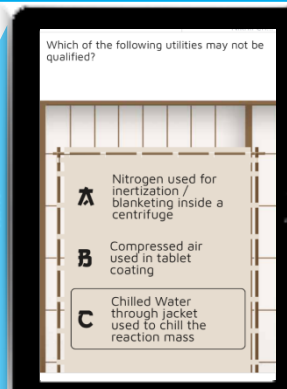
- Need identification
 - Assessment to prioritize skills & expectations for the participants
 - Developing content around addressing the need
- Class room training to learn theory & study case examples
- Live case study: Practice skill solving a live case study
- Breakthrough project: Apply combination of multiple skills to deliver impact & reinforce skill

Use digital tools to scale & sustain individually customized capability building

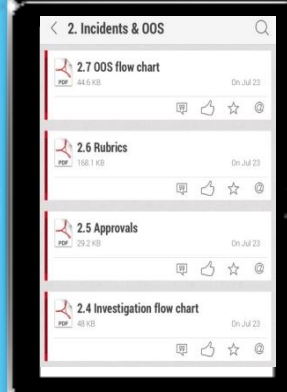


Key Features

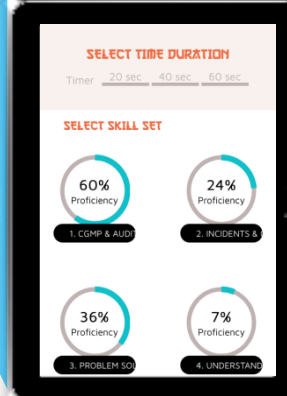
- Based on **principles of gamification**
- Easily accessible **on-the-go through smartphones**
- **Customized** to an individual's needs




- Quiz: Multiple choice questions to **test understanding**



- Knowledge nuggets: Theory on subject to **'read & learn'**



- Challenge: Users challenge each others for a time trial

 Use advanced Analytics; it helped identify ~10% of tests likely to contribute to ~60% of future invalid OOS; 35% reduction in OOS within 1 month of implementation



How it was done?



Hypothesis generation



Validation of hypotheses against data



Decision tree to identify reasons



Recommendations on allocation of rules



Details



50+ hypotheses generated based on CFT workshops, historical data (e.g. logs, exit interviews) & expert inputs



35+ data sources leveraged:

- Digital data from central systems (e.g., LIMS)
- Manual data (e.g., exit interview notes)
- External data (e.g., date-wise weather patterns)



▪ Created and tested **3,500+ univariate features** and 10K+ multi-variate features



Impact?

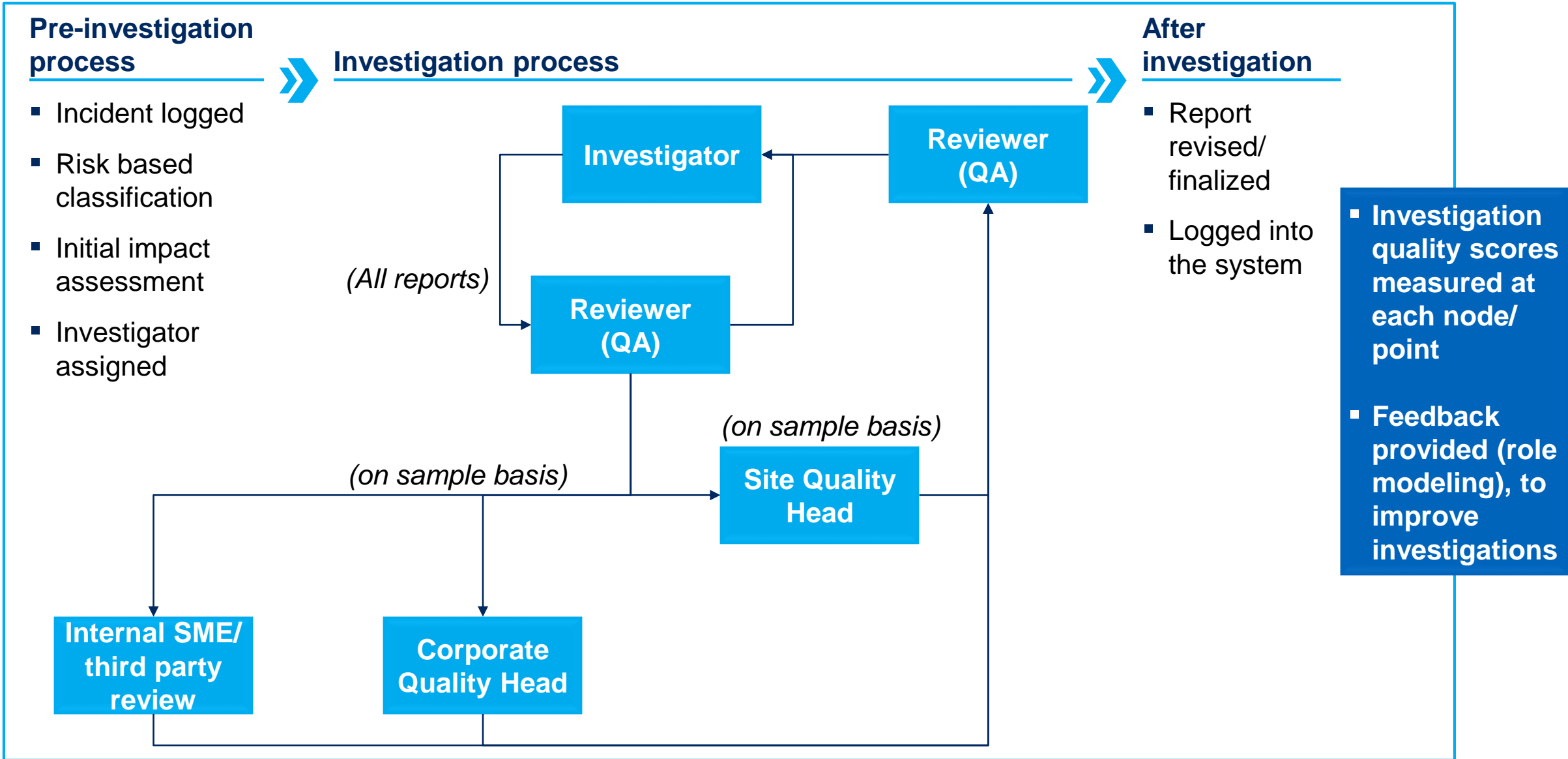


~9-12% of product-test combinations identified which account for ~60% of potential invalid OOS in the next month



35% reduction in overall OOS within 1 month of implementation

Continuously improve investigations with best practice feedback loops – Simplified



THANK YOU



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Appendix

Quality culture survey, focused group discussions and interviews identified the mindset shifts for a client and the impact was measured through monthly pulse check

