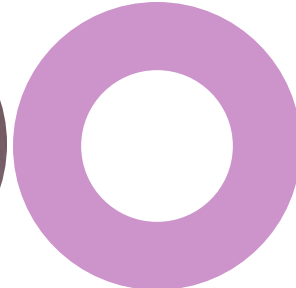


Session 6.2

Main Challenges Slowing Your Digital Validation (and How Top Teams Are Solving Them)



Panelists



Darragh Boyle
Manager, Consulting

Kneat

Clare Hehir
CSM

Kneat

Andy Clarke
Director,
Customer Success

Kneat

Gisele Fahmi
Director, Content & Risk
Management
Solutions Lead,



Session Overview

"A panel-led, slide-light conversation shaped by your responses to our opening poll"

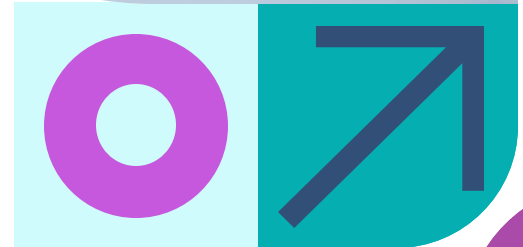
- **Poll Input:** Your responses define where we start
- **Panel Insights:** Guided by lived experience
- **Flexible Flow:** We follow the topics that matter most to you!



Poll

What is the biggest challenge slowing your Digital Validation rollout today?

- **A)** Scaling the solution
- **B)** Accelerating Go-Live / Launch
- **C)** Optimising Our Use of Kneat
- **D)** Global rollout strategy
- **E)** Knowledge / Training



Panel Discussion

Scaling Digital Validation



Scaling Digital Validation



Before scaling, do we have:

Validated process model

User roles and permission structure

Validation approach – what disciplines?



Understand what needs to be standardised vs. localised

Global: workflows, data definitions, system configuration, validation strategy

Local: site specific SOP, local regulatory add-ons, language, local risk assessments

Scaling Digital Validation



Creating a global governance model

Global process owner; digital validation steering committee; change control process; Site SME; Harmonised training model



Rollout

Site readiness assessment; Gap analysis; Hypercare period post go-live



Embracing Digital

Share success stories; create Communities of Practice

Scaling Digital Validation

2025 State of Validation: In your opinion, what are the leading benefits of digitalizing validation? Rank all answer choices in order of preference, with 10 being the highest.



Enabling global standardization:
Respondents place strong emphasis on **enabling global standardization** and **having a system of record**, highlighting a desire to harmonize validation processes and eliminate site-level silos.

Panel Discussion

Accelerating Go-Live



Accelerating Go-Live (Past Experience)

Highly specific
templates

No internal
communication

Lack of buy in –
preference for
other products etc.

Untrained access
to system

Accelerating Go-Live (Where we see Success)



RIGHT FIRST-TIME
TEMPLATES



STAKEHOLDER
ALIGNMENT – RIGHT
PEOPLE IN PLACE



COMMUNICATION
PLAN



SUPPORT STRUCTURE



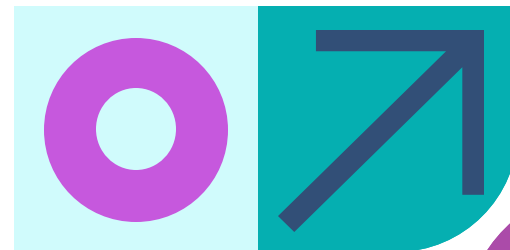
FUTURE PLANNING
(THINK OF NAMING)



TRAINING &
ONBOARDING



CONTROLLED
PERMISSIONS

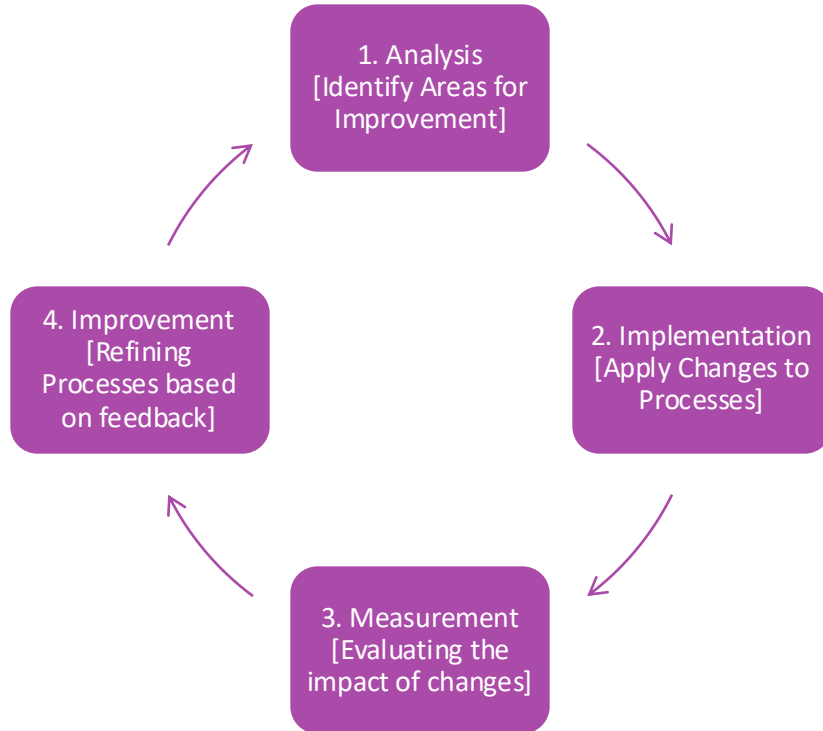


Panel Discussion

Kneat Optimization Strategies



Kneat Optimization Strategies



Optimization is a Continuous Cycle

Measure your improvements

Don't Stop There

Kneat Optimization Strategies

What does optimizing mean for you?

Early

- Deploying
- Establishing Governance
- Migrating

Maturing

- Harmonizing
- Optimizing Processes
- Expanding
- Connecting / Integrating

Prioritize the opportunity



Gather feedback from stakeholders



No “one size fits all”,

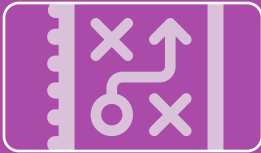


Don't boil the Ocean



Kneat Optimization Strategies

Key Success Factors



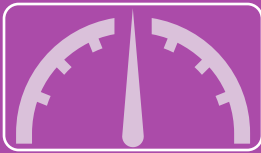
Have a Success Plan

- 5W1H: What, Who, Where, When, Why, How?
- Document it, agree it and communicate it



Identify the Team & Execute

- Engage Key Stakeholders, early and often
- Ensure the right Kneat Expertise



Measure the Success

- How successful was the optimization
- Were goals from the success plan achieved



Continue to Improve & Enable

- Establish improvement processes
- Seek continuous feedback
- Enable Users

Panel Discussion

Global Rollout Strategy



Operationalising Global Kneat

Success is embedding Kneat as the global validation operating model

- **Key Challenges:**

- Kneat is "Live" but not yet operationalised
- Strong process at pilot site but weaker globally
- Sites using it differently
- Templates not standardised
 - updates become laborious and difficult to manage
- Benefits not fully realised
 - speed and consistency

Operationalising Global Kneat

Success is embedding Kneat as the global validation operating model

- Supporting users in different regions and time-zones
- Ability to triage what is application question from a useability question
- Upgrade Support and Roles

Operationalising Global Kneat

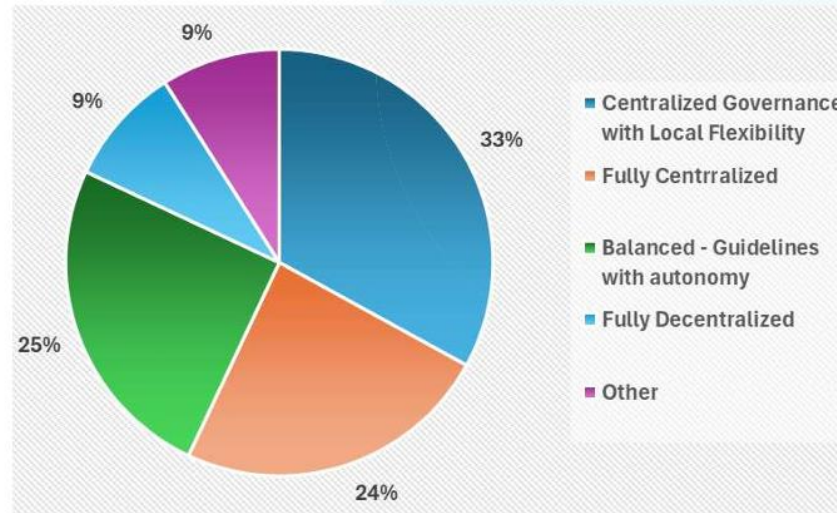
Success is embedding Kneat as the global validation operating model

- Centralised IT Support
- Standardised Validation approach
- Global Templates
- Governance
 - Global Business Owner
 - Global System Owner (CSV Owner, CQV Owner, CV Owner)
 - Global IT Owner

Operationalising Global Kneat

2024 State of Validation Report: Governance

Q: Do you have a global approach for governance of the digital validation system, or do you let sites configure the system to their specific needs?



Panel Discussion

Knowledge/ Training



Knowledge / Training

- **Kneat Academy**
- Standardised training courses covering the fundamentals of the application across all user levels.
- Data reporting enables our customers to track training levels, consumption rates, version control which provides 360 view on user competency levels – critical for platform user uptake.
- Simulated platform - Access End User training at your own convivence, progressing through as your workload permits.
- Reduction in duration of End User course (2026 = 4 hours)
- Number of languages provided (Audio translation included from June 2026)
- Kneats extensive partner network facilitates extensive reach, including time-zone, onsite, and process specific training etc.

Knowledge / Training

- **New Booking Form**

- New User-friendly simplified booking process – [Form](https://Kneat.com/academy/academy-booking-form/) (Kneat.com/academy/academy-booking-form/)
- Automation – example - users can be locked to specific versions

- **E-Learning Courses**

- Review & Approval training – 10 minutes
- Administration training – 30 - 40 minutes
- Entities Training – 2 hours
- End User - 4 hours (2026 End User – April 2026)
- Plus an additional optional “Advanced” module (May 2026)

- **Instructor Led Training Courses**

- Review & Approval training – 10 minutes
- Administration training – 30 - 40 minutes
- Entities Training – 2 hours
- End User - 4 hours (2026 End User – April 2026)
- Plus an additional optional “Advanced” module (May 2026)

Have you signed up?

Kneat's **Free Health Check** can baseline your process against industry best practices and provide a roadmap for optimized performance

