

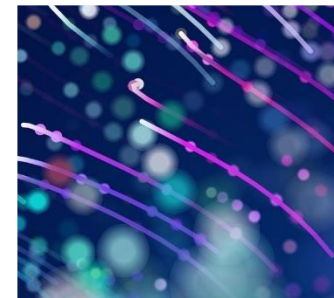


Operationalizing ICH E6 R3: A Risk-Based Blueprint for Data Management

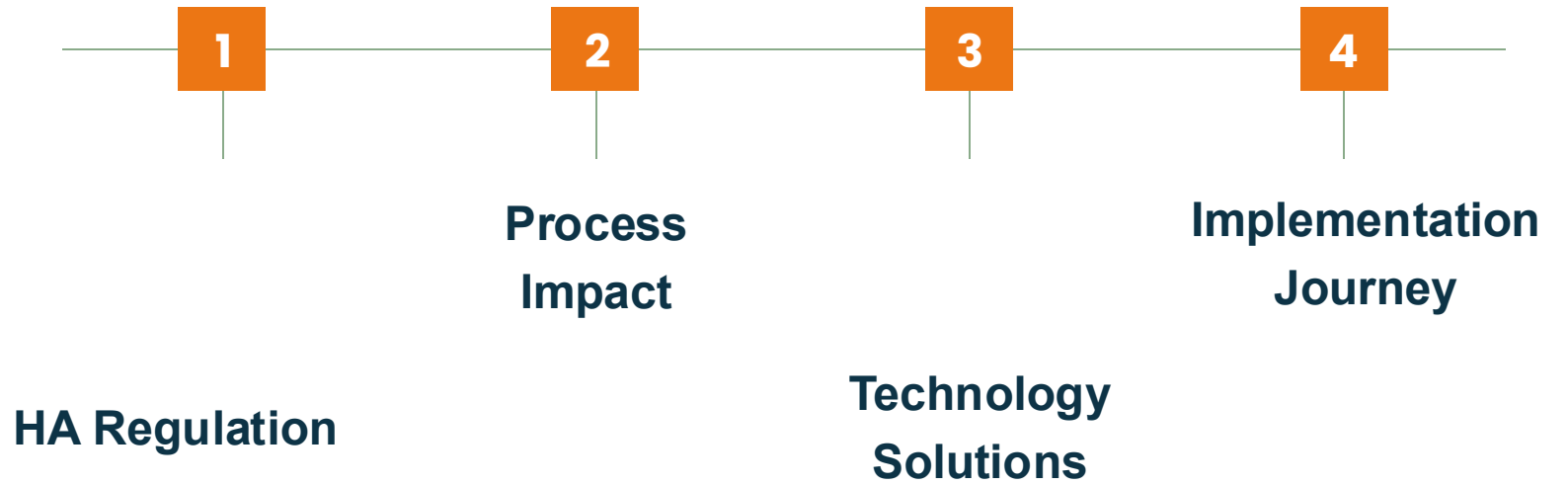
Vera Pomerantseva

Director, Risk Management Product
eClinical Solutions

PHUSE US Connect, March 2026



Presentation Agenda





PROTECTION



DOCUMENTATION



SCRUTINY

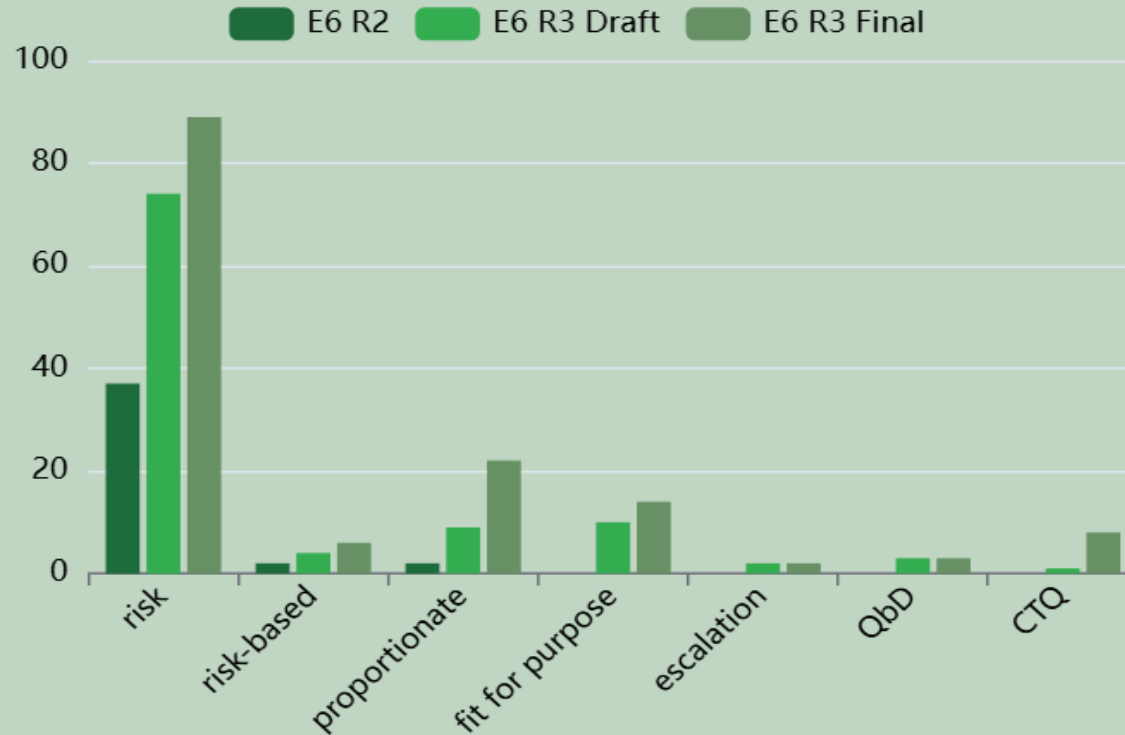


INTEGRATION

HA Regulation

Evolution of HA Regulation towards Risk Management

ICH E6 Versions Comparison



Drastic Increase of risk management terminology

*Increased by over 140% from R2 to R3
Introduced new risk mgmt. terminology*



Expansion and Integration

From monitoring to everything

Global HA Regulatory Alignment



Medicines & Healthcare products
Regulatory Agency

“The **monitoring strategy** (e.g. data management plan, medical monitoring plan, safety plan, monitoring plan etc.) are recommended to have been **based on risk assessments** “



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

“Perfection in every aspect is rarely achievable. The **quality factors** should be prioritized.”



U.S. FOOD & DRUG
ADMINISTRATION

“Within clinical trials, **monitoring and data management** processes are the main quality control activities.”



Major regulators are reinforcing consistent risk-based frameworks and integration across functional areas

Core Expectations



**Process
oversight**



**Planned audit
trail review**



**Governance
and
escalation**



**Service providers'
oversight**



**Activities driven by
risks**

**Read ICH E6 R3
in conjunction
with other
applicable
regulations: ICH
E8 R1, MHRA
and others**

What does it mean to us?

Refine Processes

Enable Technology

Empower People





PROTECTION



DOCUMENTATION



SCRUTINY



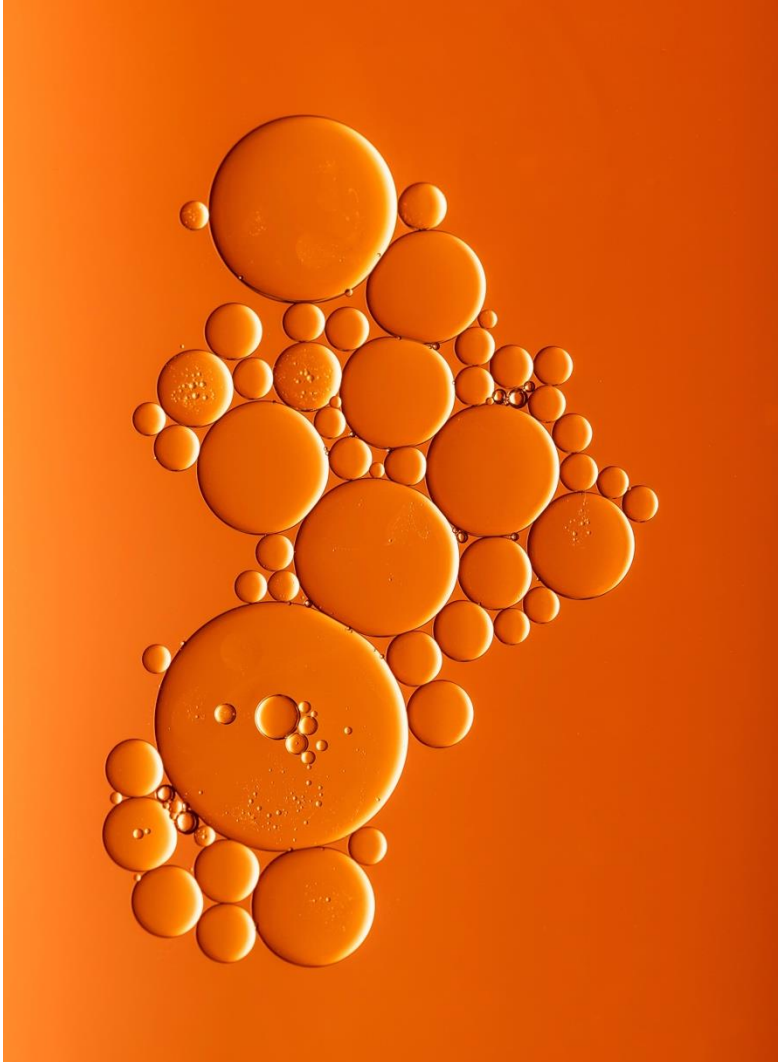
INTEGRATION

Impact on process

Back to 2015

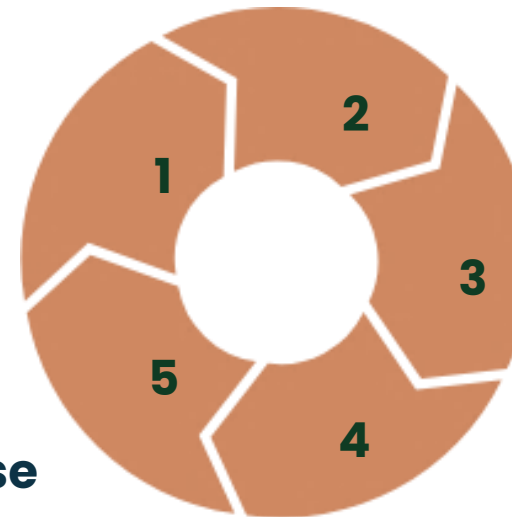


Impact on the process



**Study &
organizational
oversight**

Review and Revise



**Integration of RACT with
cross- functional plans**

**Flexible
execution driven
by risks**

**Governance and
Escalation**

Integrated RBQM across Planning, Execution, Oversight



Planning

Prioritize study risks

Connect risks to review and monitoring activities

Link data across criticality tiers with the defined activities



Execution

Conduct review and monitoring as per the plan

Track activities status across risk tiers

Detect systematic data quality risks



Governance and Oversight

Portfolio-level oversight

Monitor risks across levels, e.g. TA, program, vendors, regions etc.

Governance, escalation and continuous improvement

What stopped us from adoption?

Complexity

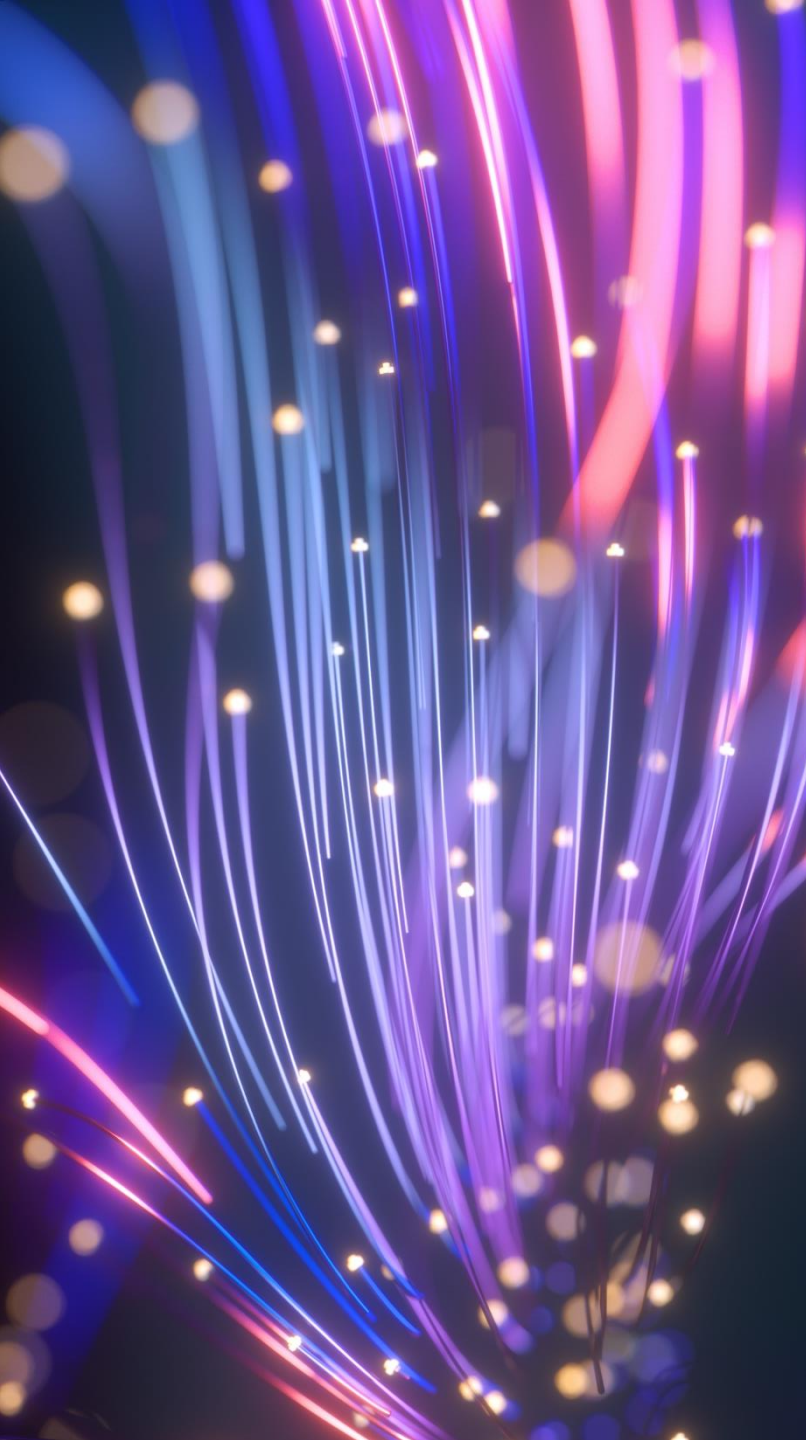
Granularity

10 years

Silos

Technology





Enablement through technology

Technology Enablement



Integrated Strategy

Risk management strategy aligned across all functions.



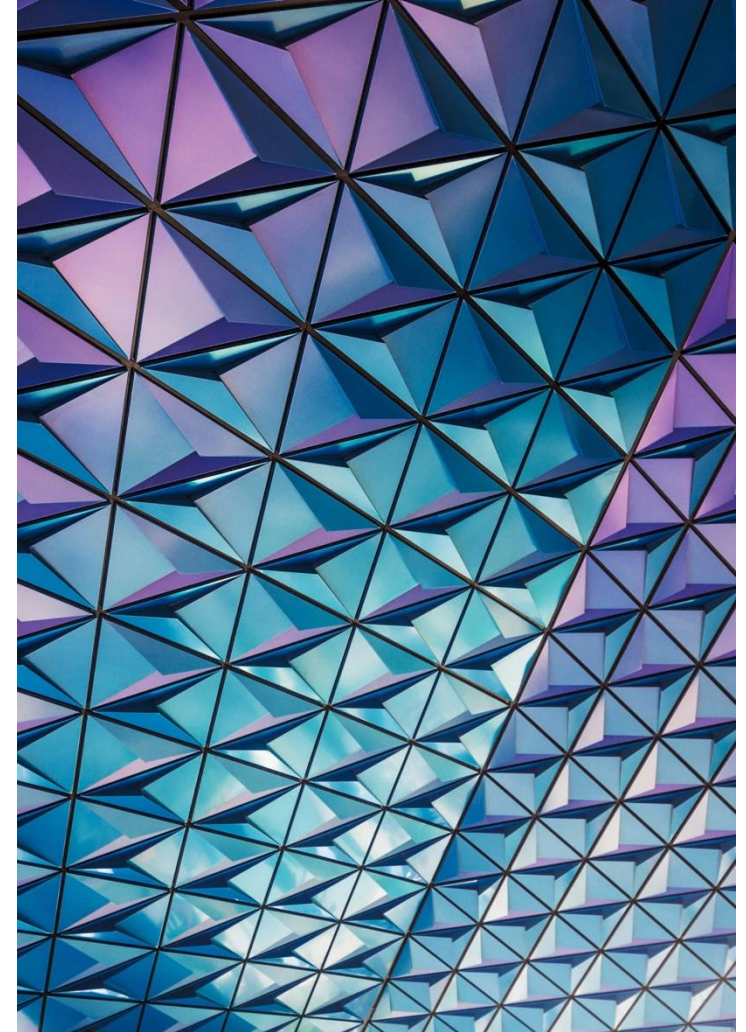
Activities & Variables Linkage

Connection between risk strategy and activities.



Single source for Data Review & Monitoring

Insight from cross functional review, monitoring and data systems

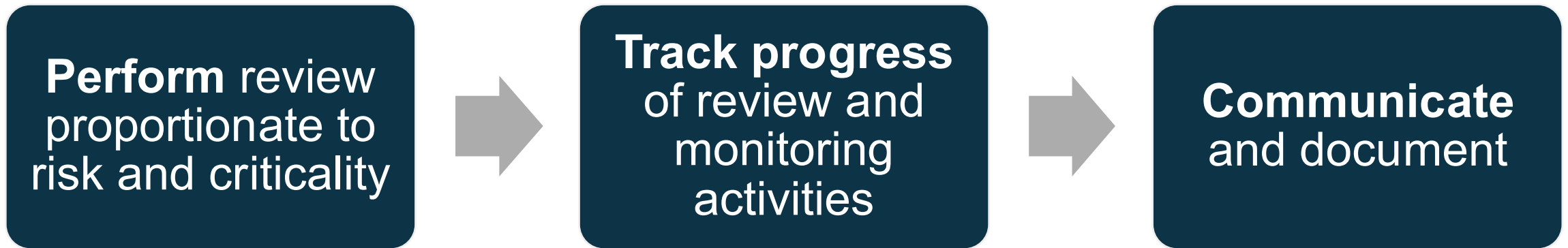


Across Planning, Execution and Oversight



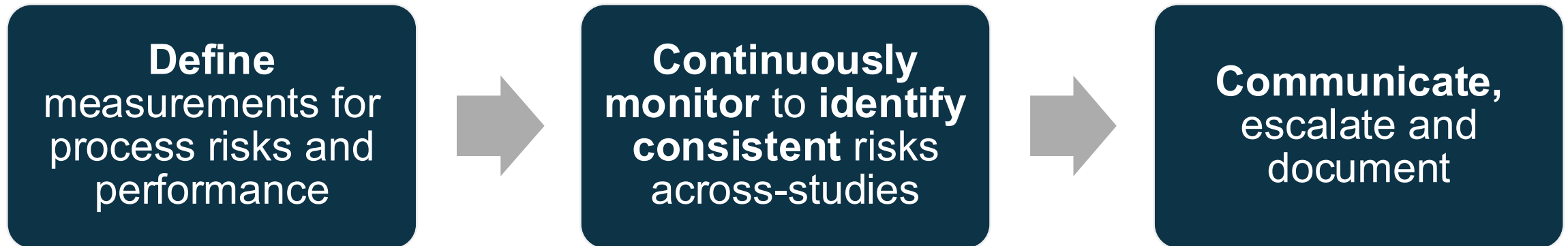
Risks → Activities → Data

Key capabilities to support ICH E6 R3



Review & communicate → Track → Adjust

Key capabilities to support ICH E6 R3



Oversee → Measure → Improve

Technology should make it easy

Connect with one click



Assessment - Version 3 In Progress 42 Consideration(s) | 56 Risk(s) | 16 Review Objective(s) Finalize

Search

View All Risks 6

Patient Safety & Adverse Event Monitoring
5 Consideration(s) | 11 Risk(s)

- ✓ C1: What mechanisms are in place to ensure real-time monitoring? 3
- ✓ C2: Is the data collected manually or electronically? 1
- ✓ C3: Is the compound a marketed product? 3
- ✓ C4: Is the risk greater than or less than the Standard deviation? 1
- ✓ C5: Safety Considerations in Clinical Trials 1
- ✓ General Risk 1

Patient Enrollment & Retention
5 Consideration(s) | 10 Risk(s)

Site Performance & Compliance
3 Consideration(s) | 9 Risk(s)

Data Integrity & Timeliness
7 Consideration(s) | 10 Risk(s)

Patient Safety & Adverse Event Monitoring
C1: What mechanisms are in place to ensure real-time monitoring, detection, and reporting of adverse events (AEs) and serious adverse events (SAEs) to safeguard patient safety and maintain regulatory compliance? + Add Risk

Risk ID: 1 Accept Score: 10

If the clinical trial lacks a robust real-time adverse event monitoring system, there is a risk that serious adverse events (SAEs) may not be detected or reported promptly, leading to potential delays in patient safety interventions. This could result in regulatory

Impact	Probability	Detectability	Overall Score:
Low (1)	Medium (4)	High (7)	Medium (50)

Risk ID: 2 Mitigate Score: 8 Review Plan

If investigative sites do not adhere to standardized AE/SAE reporting procedures, there is a risk of inconsistent data capture and delayed regulatory submissions. This may compromise patient safety, impact trial credibility, and introduce regulatory penalties,

Impact	Probability	Detectability	Overall Score:
Low (1)	Low High (3)	Low High (3)	Low (10)

Risk ID: 3 No control defined Score: - Incomplete

Impact	Probability	Detectability	Overall Score:
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Data Review Plan

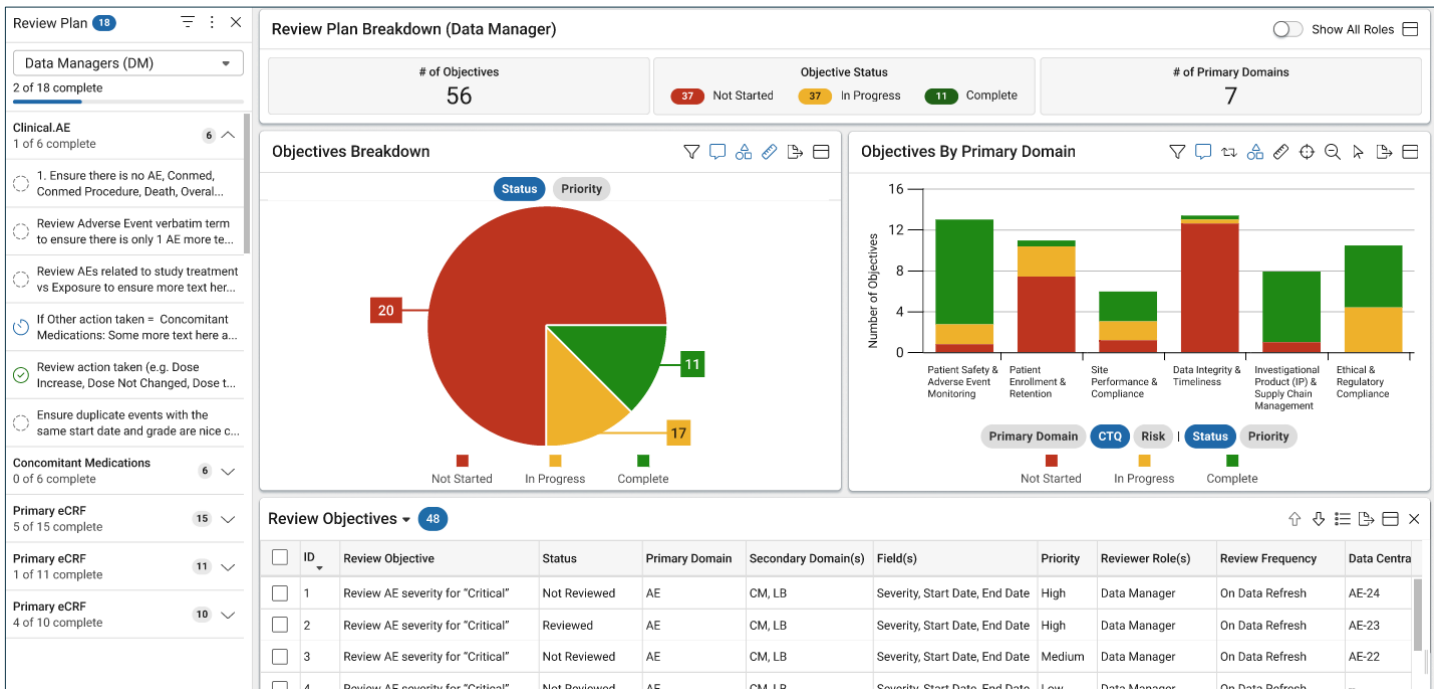
Medical Review Plan

Safety Review Plan

Monitoring Plans

Technology should make it easy

Track and Monitor progress



Medical Review

Data Review

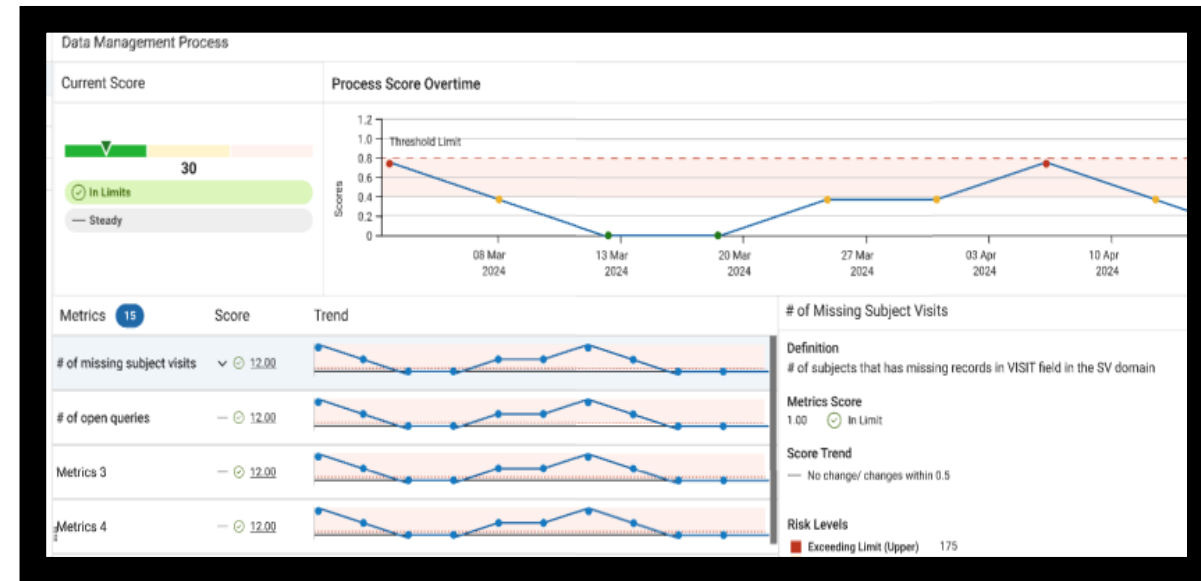
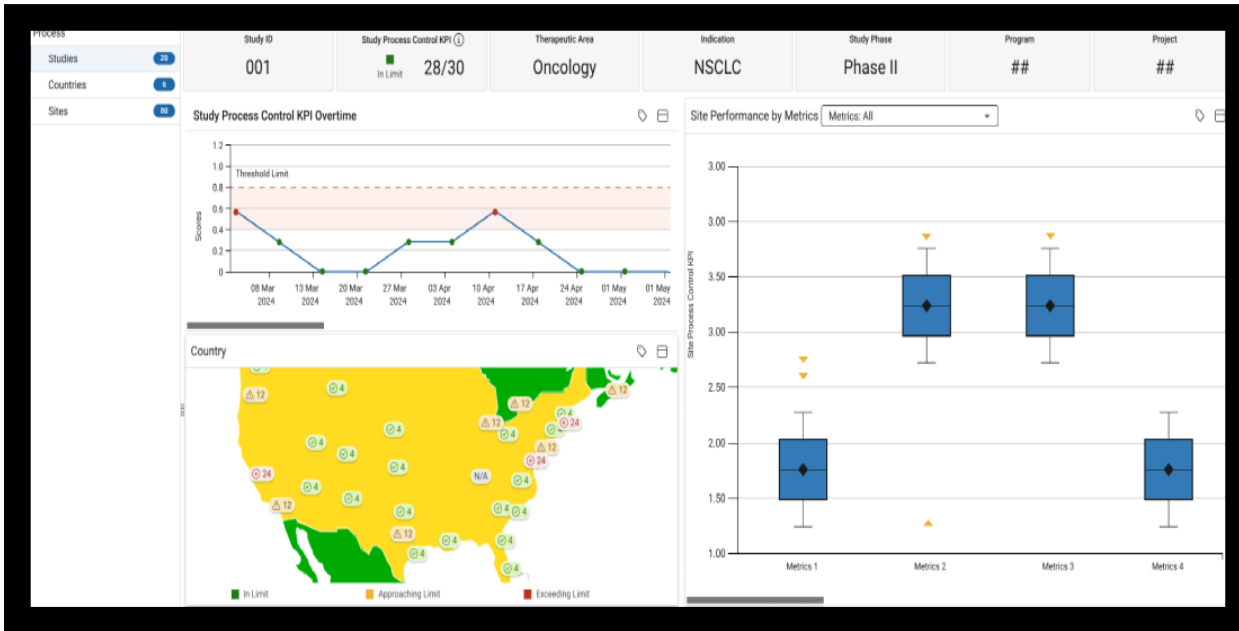
Safety Review

Issue Text	Status	Criticality	Priority	Due Date	Opened By
Issue # 1	Closed	N	Priority 1	23 Oct 2024	admin
Issue # 2	Closed	Y	None	19 Mar 2019	admin
Issue	Closed	N	Critical	19 Mar 2019	admin
werfghjk	Closed		Moderate	12 Oct 2024	sunil2
werfghjk	Canceled		Major	21 Mar 2019	sunil2
please confirm. this seems off to...	Open		Critical	16 Apr 2019	lclough2
Raising an issue on this query, ha...	Closed	N	None	24 Aug 2019	Admin
here is a test issue with legacy D...	Open	N	Moderate	24 Sep 2019	KTHOM...
Here is a domain issue	Open		Moderate	25 Sep 2019	KTHOM...



Technology should make it easy

Process performance oversight



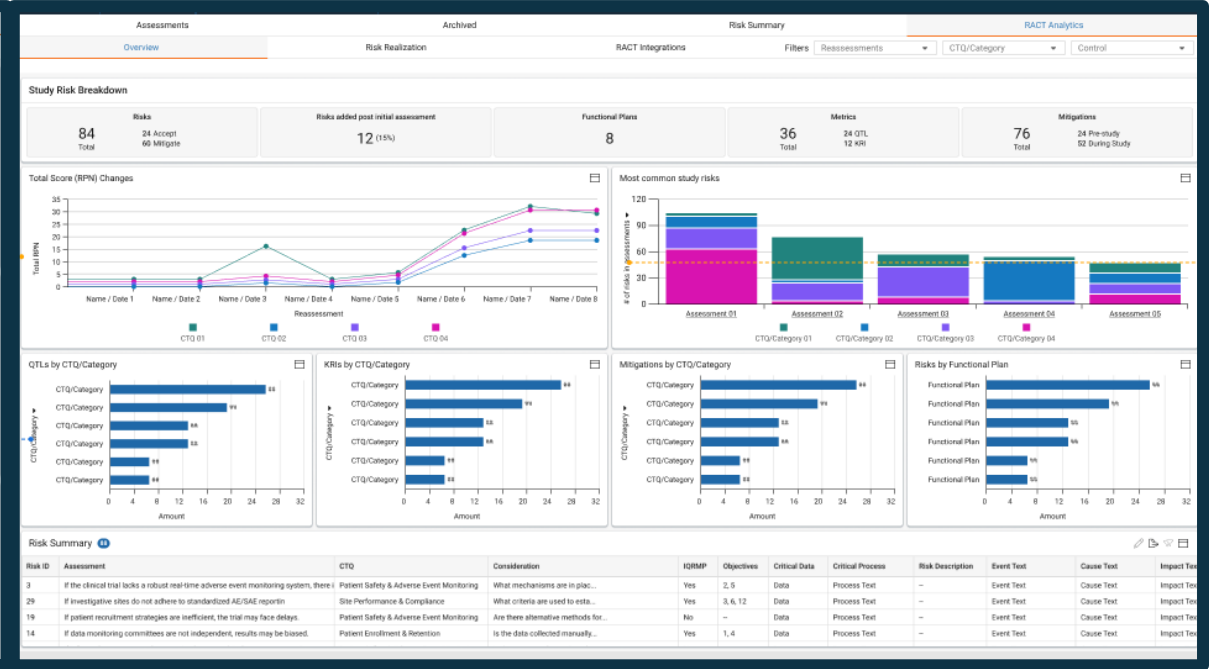
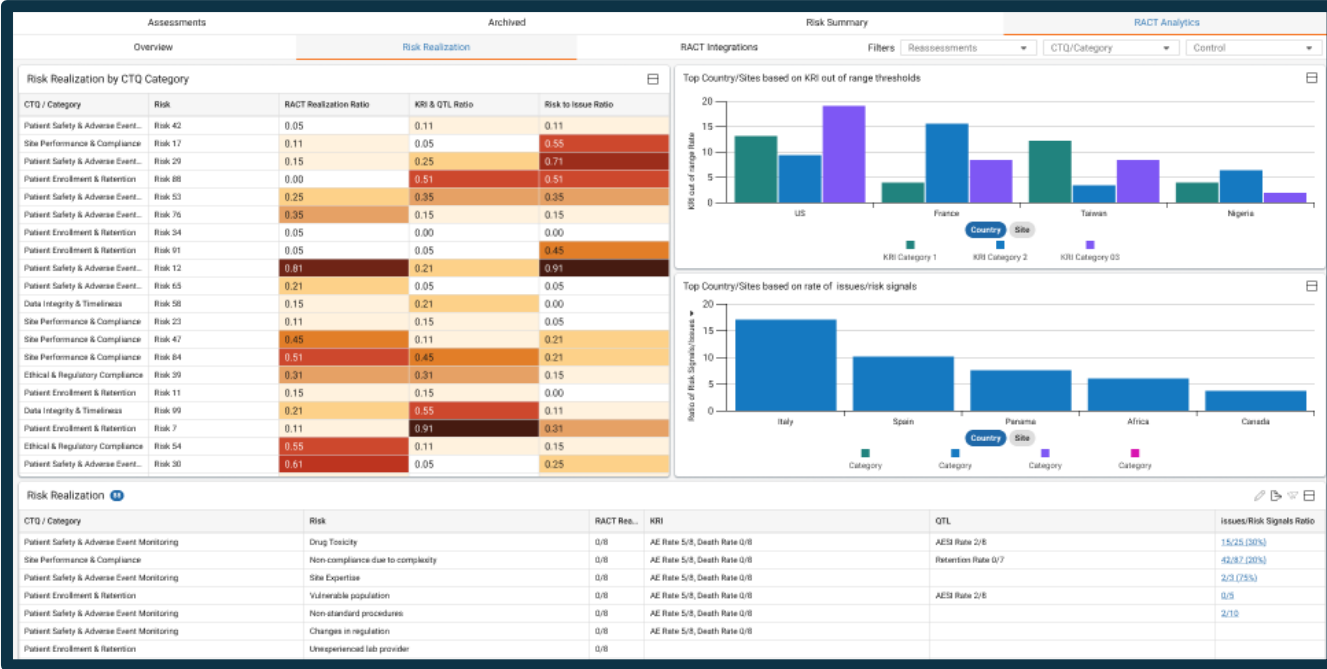
Performance Risks

Across studies process risks

Time trends

Technology should make it easy

Risks oversight



Highest Areas of Risks

Risk Realization

Escalation points

Silos and Workload

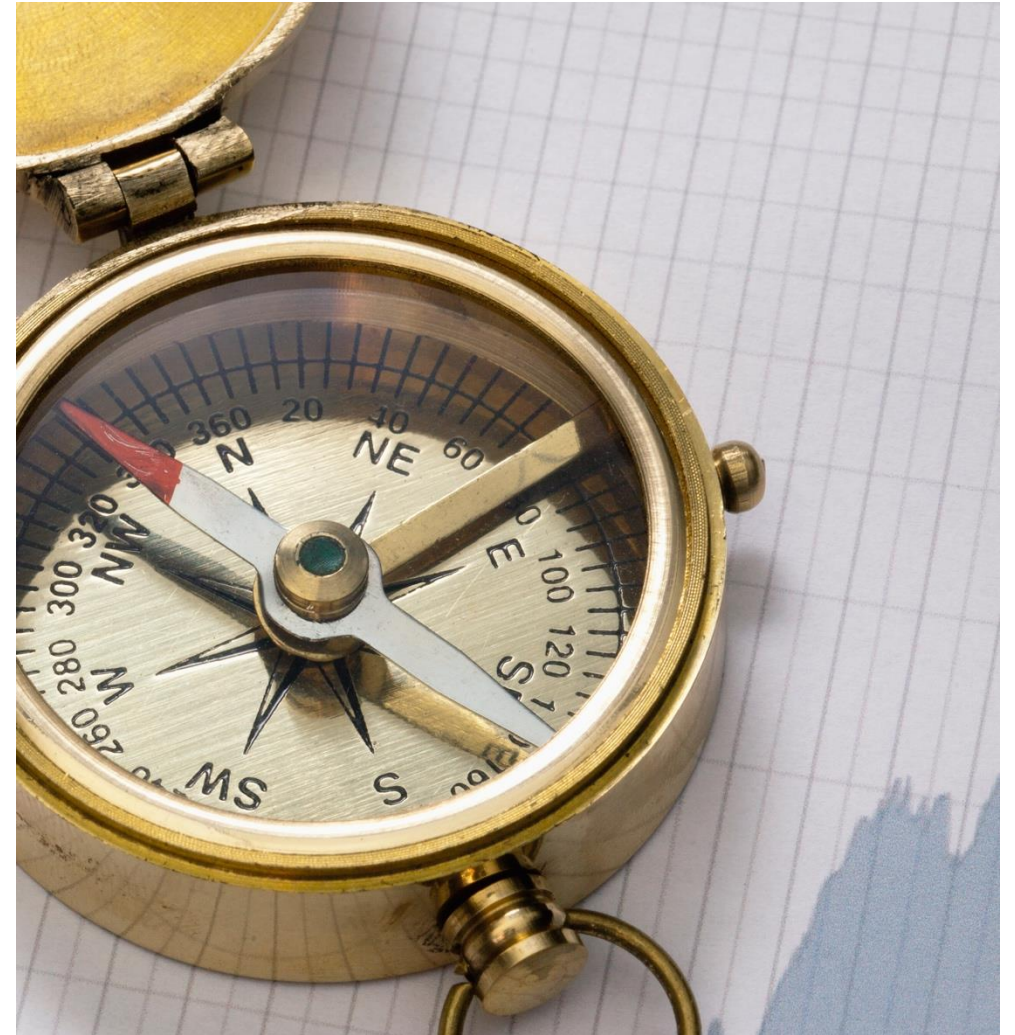




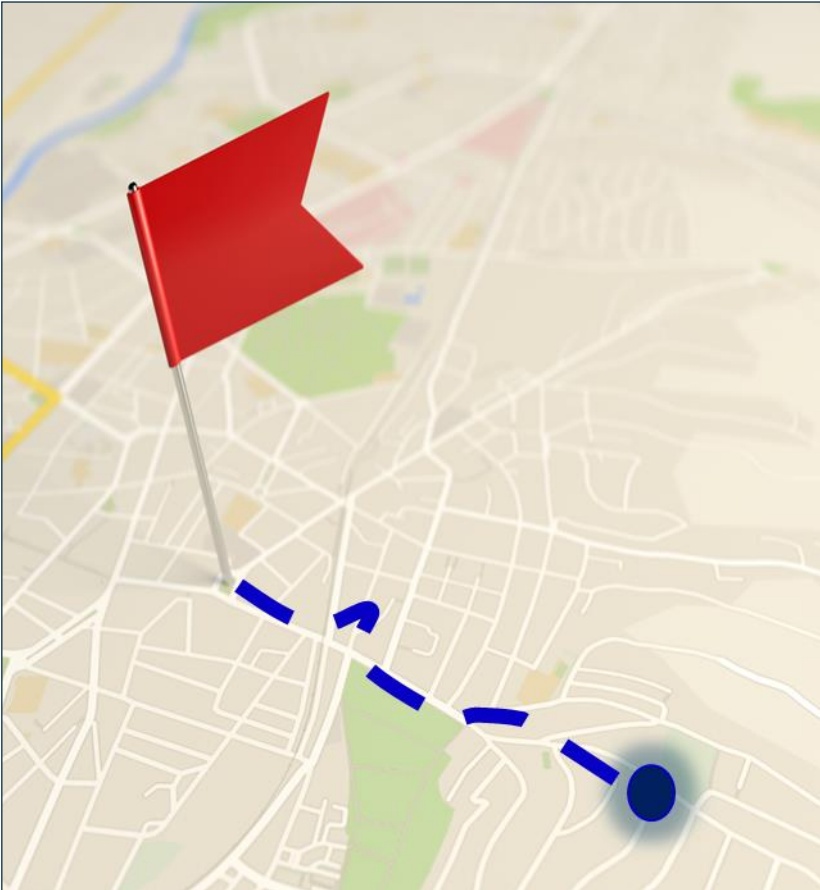
Where to start

■ Create your own GPS

- Define your Northern star (**Destination**)
- Assess your maturity (**Current Location**)
- Identify gaps (**Calibrate current location**)
- Create implementation roadmap (**Build the way and the route**)
- Start with pilot (**Start**)
- Learn and implement broadly (**Check and Continue**)



Defining Destination and Location



Recommended Scale: Never, Rare, Most of the time, Always

Planning:

- Initial protocol risk assessment
- RACT integration into functional plans
- Defined risk mitigations and controls

Execution & Closeout:

- Data review activities driven by risks and criticality
- Process review including vendor Oversight
- Metadata & Audit Trail Analysis
- Continuous Reassessment and adjustments
- Reduce SDV/SDR activities

Oversight & Improvement:

- Portfolio-Level Process Oversight
- Defined Escalation Pathways
- Continuous Improvement
- Governance

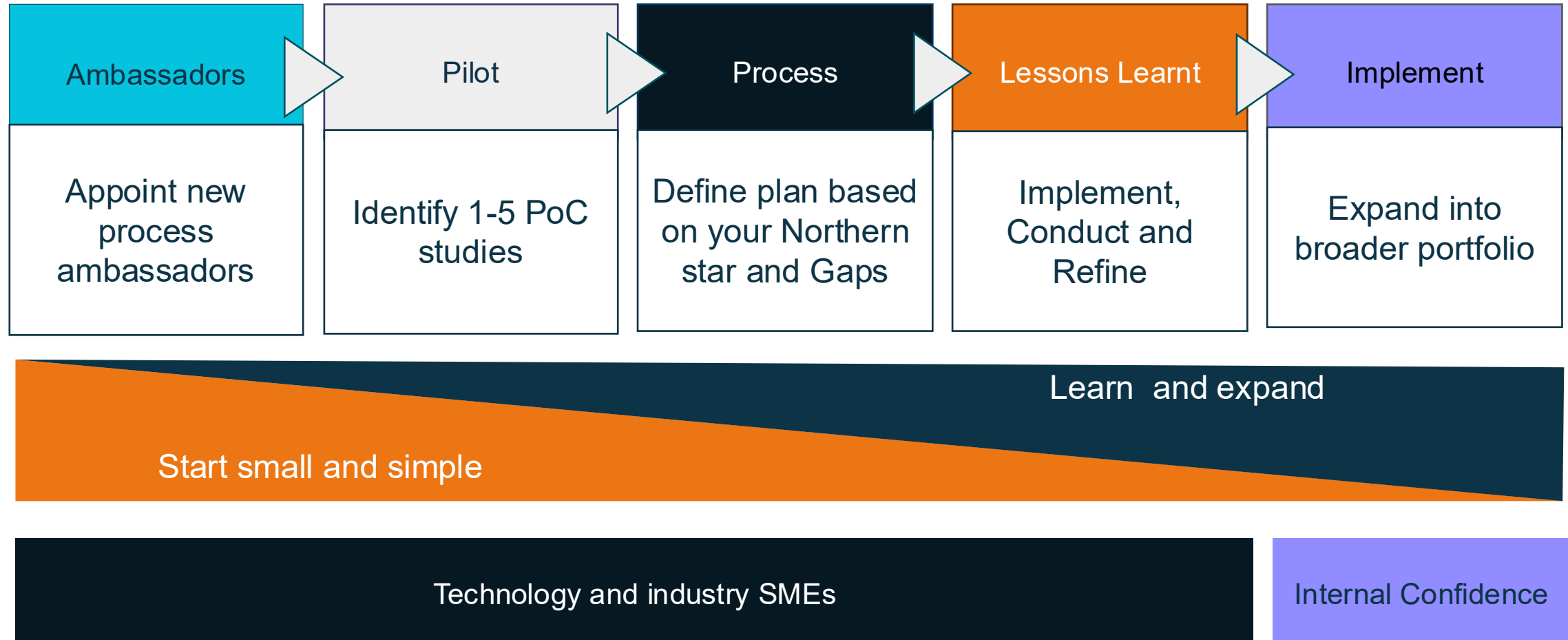


Print me !!!



Implementation Plan

Tailored approach based on adoption maturity



Contact information

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eClinical Solutions

For more information about the illuminate platform, RBQM implementation strategies, and risk management processes, please reach out.



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[eClinical Solutions](https://www.linkedin.com/company/eClinical%20Solutions)

