

# MANAGING **DISRUPTIVE** COMPLIANCE CHALLENGES

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# INTEGRATED PROJECT MANAGEMENT CO.

*Experts in Life Sciences Industry Project Leadership + Consulting*

## PRESENTERS

**Scott Babler**  
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Director  
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## IPM QUICK FACTS

**500+**  
clients, from Fortune 100 to start-ups

**5,000+**  
projects, nationally + internationally

**90%**  
repeat business

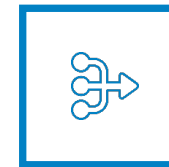


Commitment to philanthropy

## IPM SERVICES



**Project Portfolio  
Management**



**Mergers,  
Acquisitions,  
Integrations**



**Product  
Development**



**Regulatory &  
Quality**



**Change  
Management**



**Business  
Technology**

# DISRUPTIVE COMPLIANCE CHALLENGES

UNEXPECTED EVENTS THAT DISRUPT NORMAL OPERATIONS



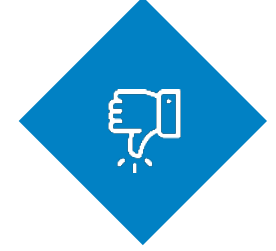
**Changing Global  
Regulatory Requirements**



**EU MDR  
Conformance**



**Legacy Device  
Remediation**



**Product Failures  
& Recalls**



**Enhanced Industry  
Standards**



**EU IVDR  
Conformance**



**Regulatory Audits  
& Findings**



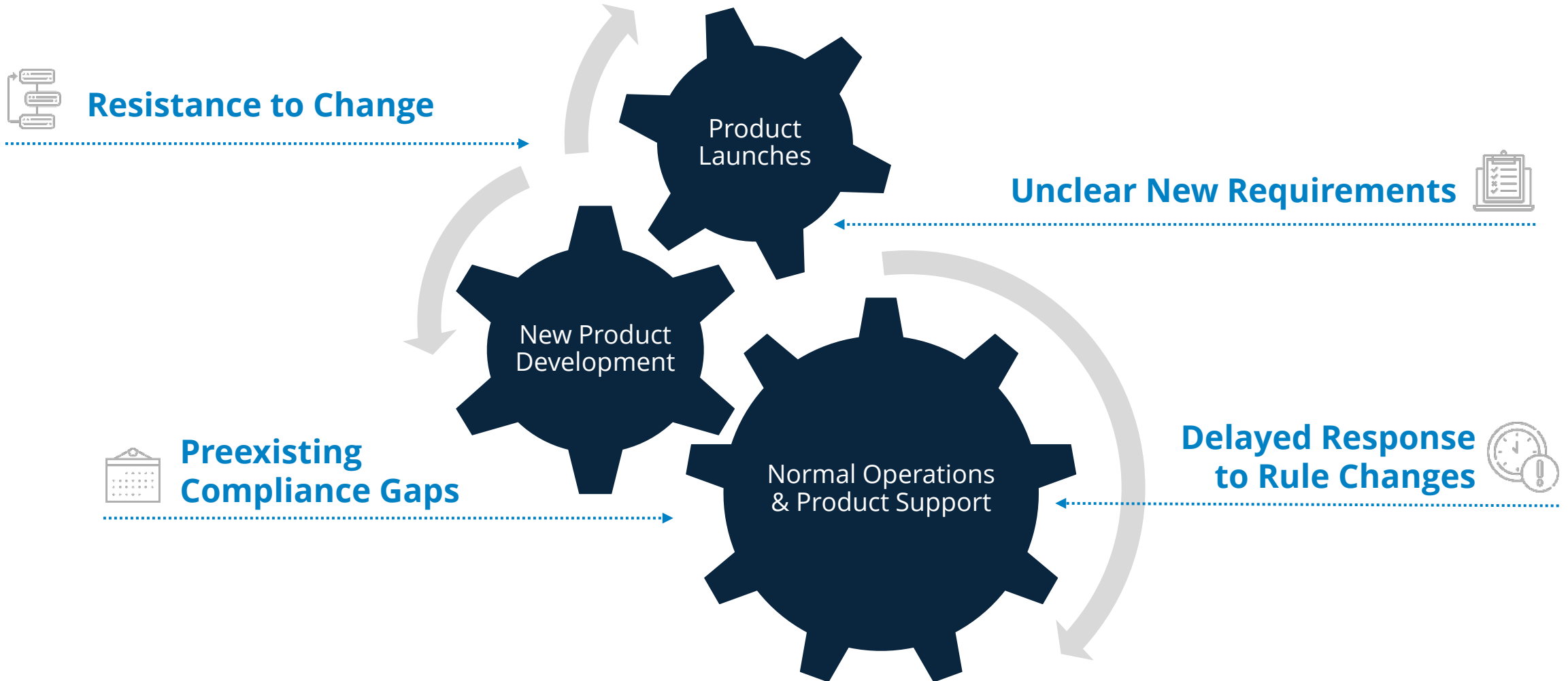
**Post-Acquisition  
Product Remediation (DHF)**



# IMPACT OF DISRUPTIVE COMPLIANCE EVENTS



# COMPANY CONDITIONS CAN INCREASE DISRUPTION OF NORMAL PROCESSES



# REGULATION CHANGES CAN YIELD BENEFITS



*Industry  
Improvements*

*Improved  
Product Quality*

*Better Systems –  
More Efficiencies*

*Reduced Product  
Failures*

*Adoption of Better  
Tools & Processes*

*Global Standardization  
Reduces Costs*

# BENEFITS RESULTING FROM IMPROVED STANDARDS

## UDI

- Global product traceability
- Tracking of implantable devices
- Better AE reporting and post-marketing surveillance system
- Market data analytics
- Standardized identifier throughout supply chain
- Counterfeit reduction

## MDR

- Single source of truth for labels and label components
- Replace manual processes and scattered databases
- Greater efficiencies and content management
- Improved decision making

## MDSAP

- More efficient and less burdensome regulatory oversight
- Single audit program acceptable
- Covers ISO 13485:2016 and 21 CFR Part 820
- Encourages better global regulatory alignment



# REDUCING THE DISRUPTION





# CREATING THE ENVIRONMENT FOR A SUCCESSFUL CHANGE

**MOTIVATE THE TEAM BY SHOWING  
BENEFITS FROM THE CHANGE**

## **ORGANIZATIONAL CAPABILITY**

- **Regulatory/quality landscape monitoring**
- **Early warning system**
- **Strong Quality-Regulatory partnership**
- **Dedicated leader to manage change**

## **ENVIRONMENT FOR CHANGE**

- **Systems and processes for change**
- **Organizational readiness for change**
- **Build in flexibility**
- **Planning for changes early**

# ***"MANAGING THE CHANGE"***

## ***Assess Impacts***

- Create stakeholder awareness
- Impacts on functions & people
- Changes to QMS & processes
- Plan level of effort, timing, budget

## ***Strategy & Planning***

- Identify & communicate benefits of change
- Change leadership
- Change management plan
- Program execution plan

## ***Implementing the Change***

- Implement communication plan
- Engage key influencers & early adopters
- Stakeholder monitoring
- Measure progress
- Benefits realization

# BUILDING AN ADAPTIVE ORGANIZATION

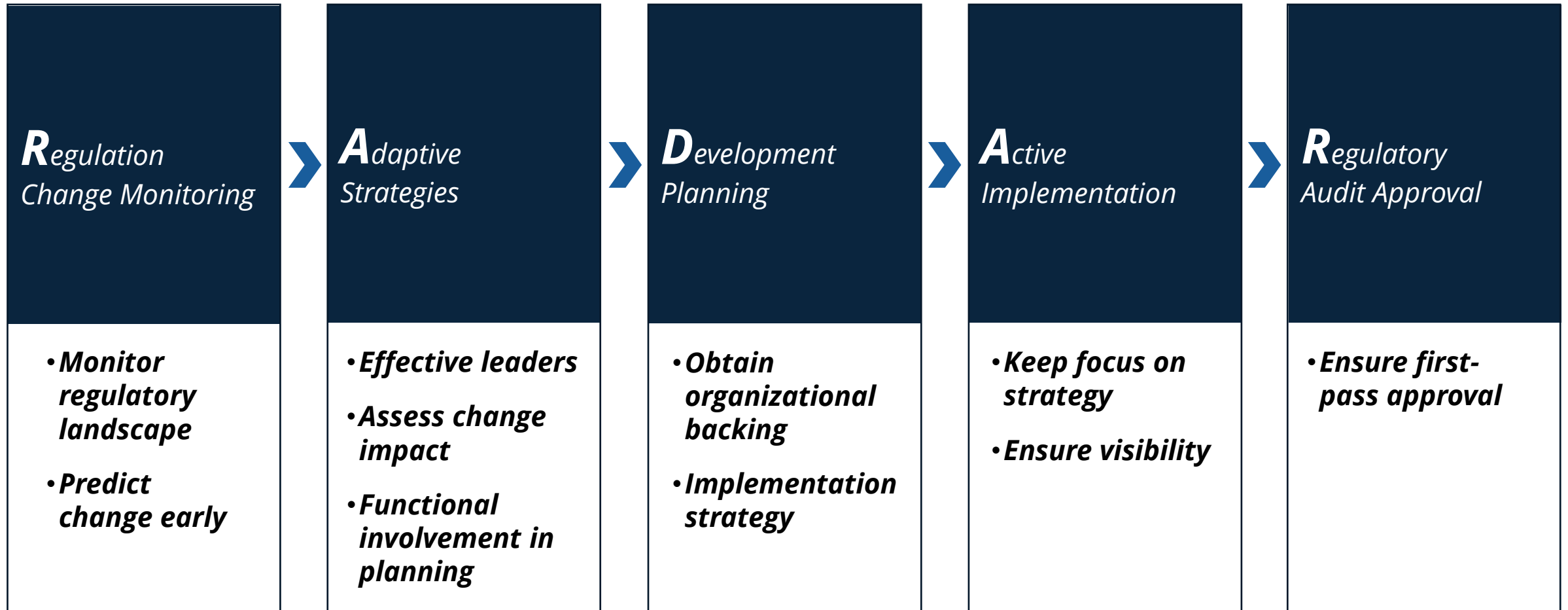
## TRANSFORMING FROM REACTIVE TO PROACTIVE

***Adaptive*** organizations continually monitor and quickly incorporate compliance activities into workflows to execute earlier





# ADAPTIVE ORGANIZATIONAL APPROACH (RADAR)



# ADVANTAGES OF ADAPTIVE ORGANIZATION

Early warning and  
extended vision

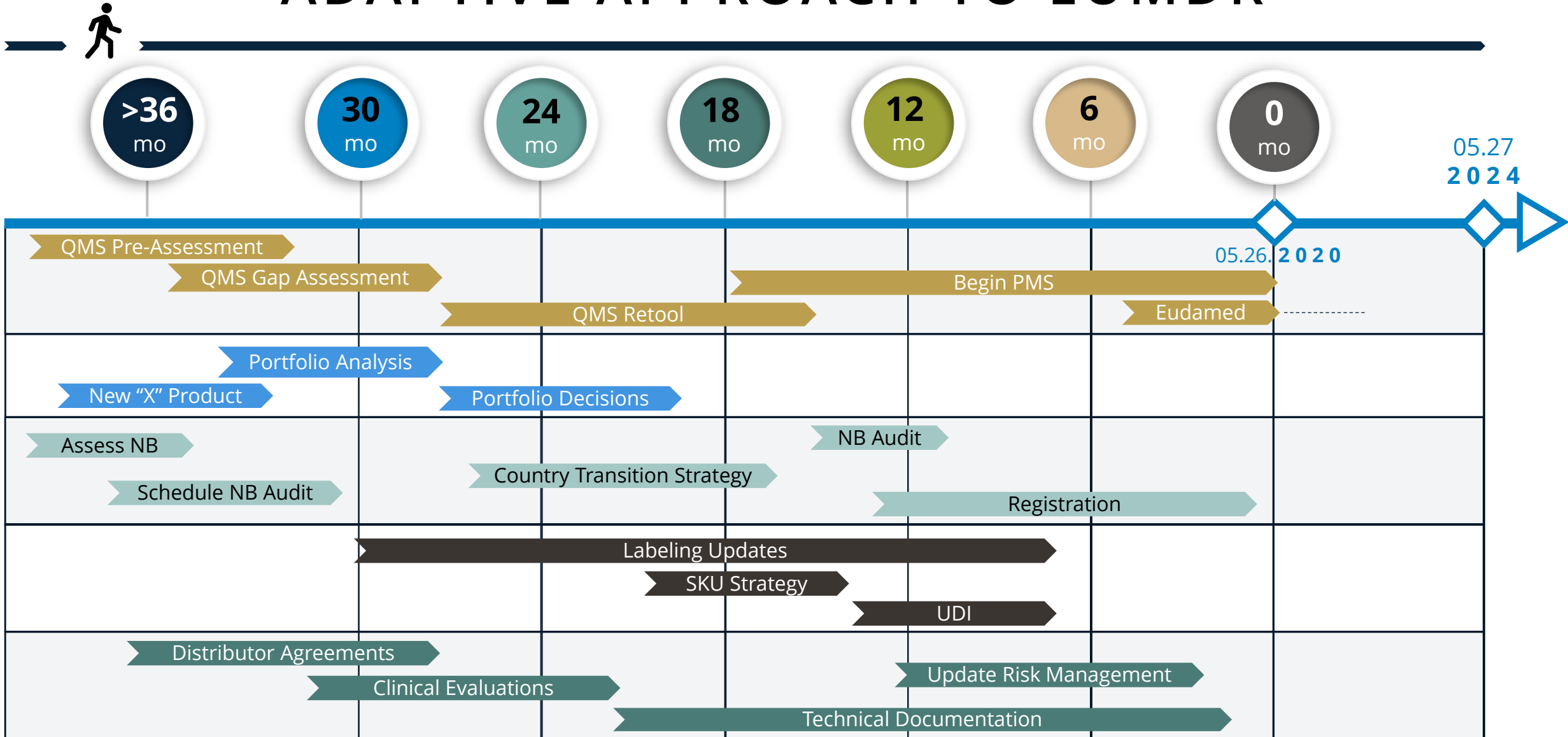
Integrated into portfolio –  
minimized disruption to  
normal operations

Project runs like any  
other project in the  
portfolio

Management  
awareness and  
support

Resourced to manage  
scope by target  
completion –  
lower stress/attrition

# ADAPTIVE APPROACH TO EUMDR





# BEING ADAPTIVE SOUNDS GREAT, BUT WHAT HAPPENS WHEN YOU'RE NOT?



*Switches the organization into a  
different mode: reactive/crisis*



*Fast paced; often  
disorganized*



*Pulls in whoever they can,  
but often the "A" players*

# ORGANIZATIONAL IMPACT OF A CRISIS



**OPERATIONAL**



**FINANCIAL**



**CULTURAL**



**REPUTATION**

# OPERATIONAL IMPACT



***Resources  
reallocated***

***Ongoing  
operations  
disrupted***

***Current  
projects  
delayed***



# FINANCIAL IMPACT



***Portfolio becomes  
unpredictable***

***Revenue  
forecast at risk***

# CULTURAL IMPACT



*Communication breakdown leads to confusion and fear*

*Negative impact on personnel*

*Reassignment*

*Stress/morale*

*Loss of key employees*

# IMPACT ON REPUTATION



*Working relationships with regulatory bodies at risk*

*Greater level of scrutiny*

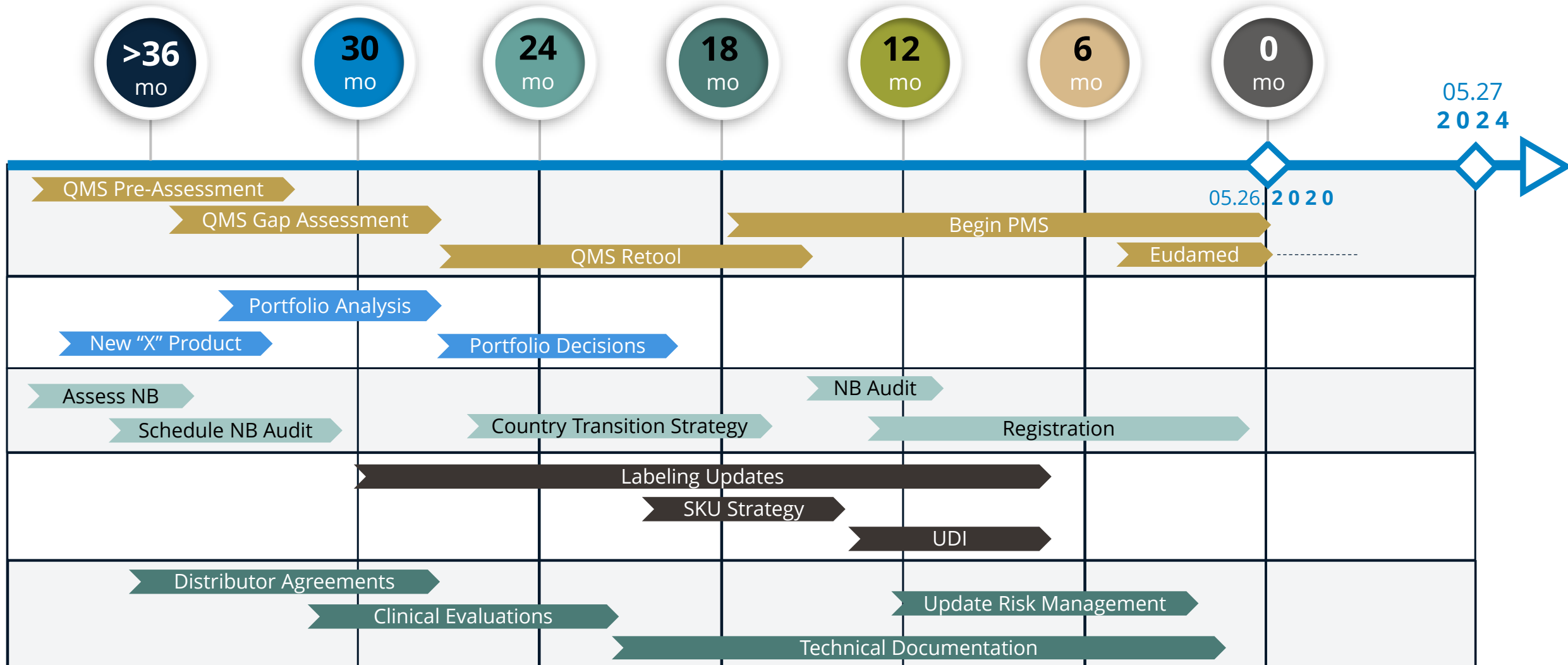
*Regulatory bodies*

*Investors*

*Personnel*



# REACTIVE APPROACH TO EUMDR



# RECOVERING WHEN YOU ARE LATE

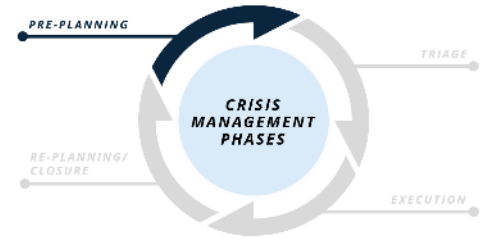
*This environment requires a different focus*  
**WHAT IS KEY**

- Triage the situation
- Management support
- Change management – rapid evolution
- Communication – urgency
- Need learned resource – call in a different team
  - *If you have a tiger team internally, deploy them*
  - *If not, seek help from outside the organization*





# PRE-PLANNING/ PRE-CRISIS PHASE



**AVOID FURTHER  
CRISES**



**MITIGATE  
IMPACTS**



**DEVELOP  
CONTINGENCY  
PLANS**

**IDENTIFY THE PERSON/TITLE  
THAT WILL DIRECT RESPONSE**

**IDENTIFY REQUIRED  
CROSS-FUNCTIONAL SUPPORT**

**WHO, WHAT, WHEN,  
WHERE AND HOW**

**WHO SUPPORTS RESPONSE  
AND WHO SUPPORTS NORMAL  
DUTIES?**

**ALLOCATE TIME AND FUNDING**



# ALIGN ON THE PROBLEM



*Understand  
the actual  
problem to  
be solved*



*Write it  
down;  
get the  
size and  
scope*



*Get  
alignment  
from the  
team*



*Get  
alignment  
with  
management*



# KEY ELEMENTS FOR SUCCESS



## *Leadership*



***Assign the  
solution leader***

***Owens the problem  
and the solution***

## *Resources*



***Dedicated***  
***Properly skilled***  
***Clear roles***  
***Tradeoffs***

## *Communication*



***Planful***  
***Transparent***  
***Consistent***  
***Cadence***

## *Planning*



***All stakeholders***  
***Ongoing operations***  
***Cultural aspect***  
***Iterate plan***

# EXECUTION



***Communication***



***Disciplined execution;  
tackle big problems first***



***Determine and solve  
the root cause***



***Fix things you can  
as you learn about them***



***Disposition task that cannot  
be fixed immediately***



***Apply change  
management***

# RESPONSE CLOSURE



*Review to ensure  
the root cause  
was resolved*

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*Update response  
procedures with  
lessons learned*

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*Review other issues  
that were discovered  
but not resolved*

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*Communicate  
the changes across  
the organization*

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*Deal with  
collateral  
damage*

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*Adjust the  
project portfolio and  
reassign the resources*

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# CRISIS MANAGEMENT PHASES CHECKLIST



## ***PRE-PLANNING***

- ☐ Risk management
- ☐ Structured response plan

## ***TRIAGE***

- ☐ Assign a leader
- ☐ Develop a communication plan
- ☐ Assign dedicated resources
- ☐ Determine root cause
- ☐ Triage the issues
- ☐ Plan cross-functional activities

## ***EXECUTION***

- ☐ Execute the plan
- ☐ Re-plan
- ☐ Communication
- ☐ Iterate the plan back to root cause

## ***RE-PLANNING/CLOSURE***

- ☐ Ensure root cause resolved
- ☐ Communicate broadly
- ☐ Apply lessons learned
- ☐ Update risk register
- ☐ Reassign resources

# KEY TAKEAWAYS



- Disruption can be reduced through early planning, right leadership, and the right strategy
- RADAR approach to build an adaptive organization
- Crisis management can help late programs recover
- Building and maintaining the right teams and processes is key whether in adaptive or crisis modes

# QUESTIONS

*Additional questions and comments can be directed to us by email.*

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