

# Focus on Patient & Product Quality as the foundation for Data Integrity

Doreen Newhouse, Global Head, Sandoz Data Integrity Office

*presented by*

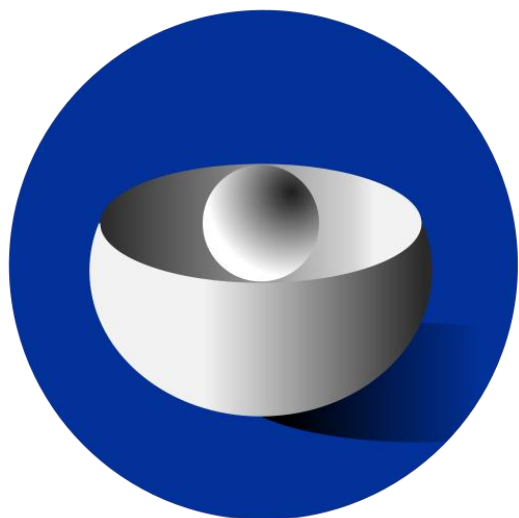
James Mann, Head Data Integrity Program Management, Pharma

Barcelona, Oct 27, 2015

# FDA Warning Letters about DI to Indian suppliers

Warning Letter Issued To	Date Warning Letter Issued
Apotex Research Private Limited	01/30/2015
Micro Labs Limited	01/09/2015
Cadila Pharmaceuticals Limited	10/15/2014
Marck Biosciences Ltd.	07/08/2014
Apotex Pharmachem India Pvt Ltd.	06/17/2014
Sun Pharmaceutical Industries	05/07/2014
Canton Laboratories Private Limited	02/27/2014
USV Limited	02/06/2014
Wockhardt Limited	11/25/2013
Agila Specialties Private Limited	09/09/2013
Posh Chemicals Private Limited	08/02/2013
Aarti Drugs Limited	07/30/2013

# EU regulators are taking strong action on DI

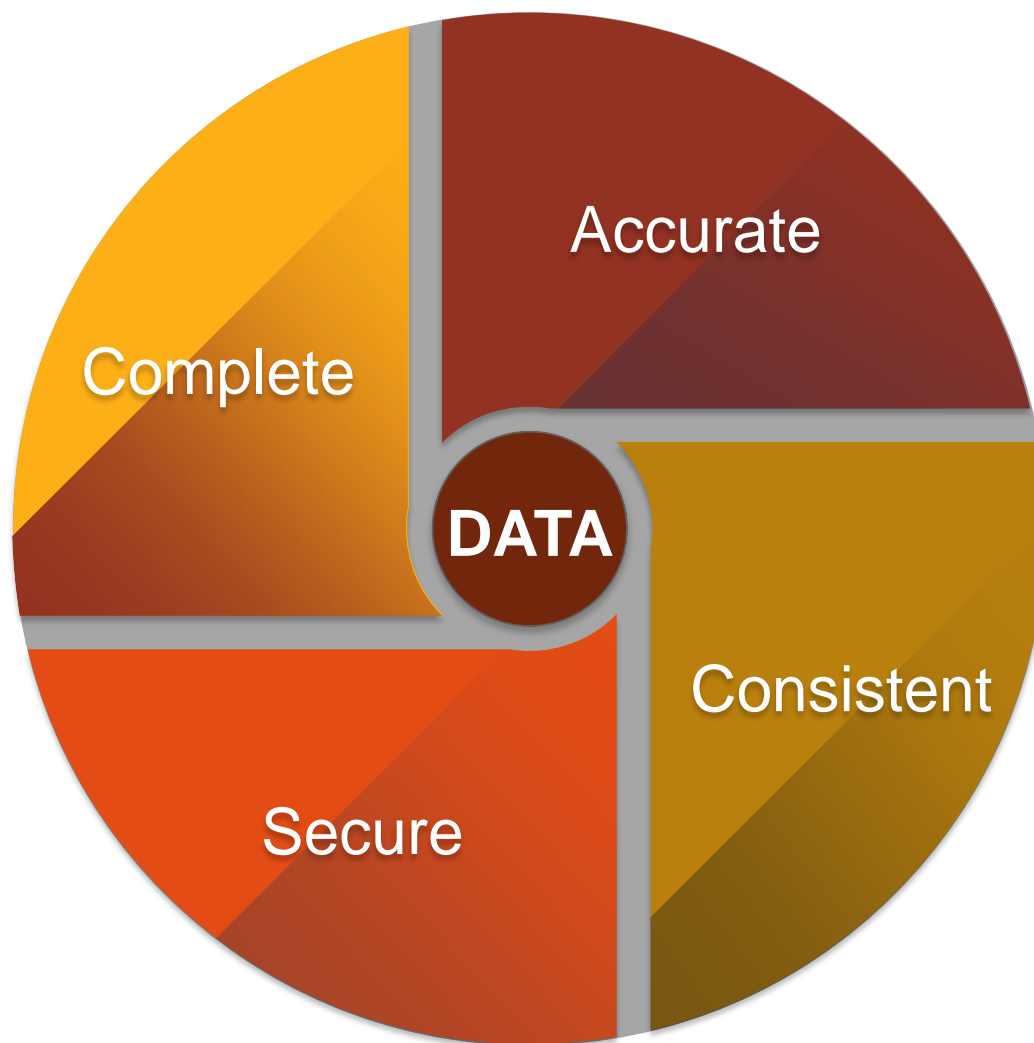


## EMA Recommends Suspending Drugs over GVK Data Integrity Issues

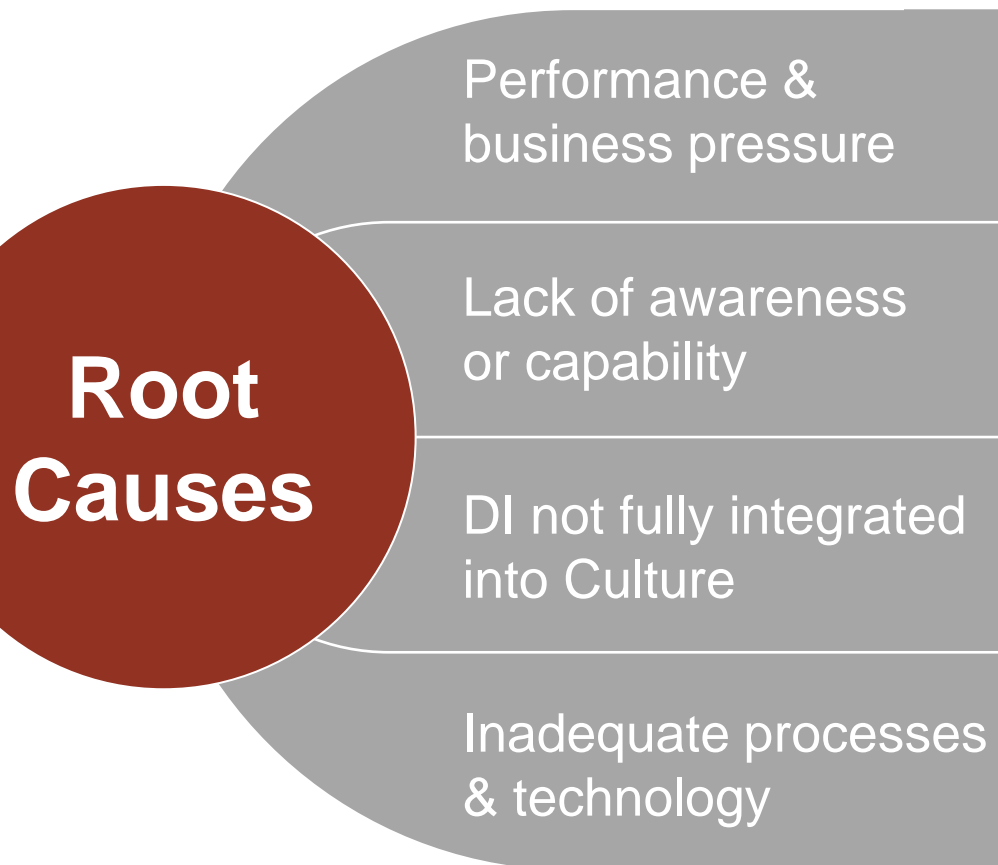
Posted 23 January 2015

More than 700 Products  
Recommended for Suspension

# Data Integrity: what are we aiming for?



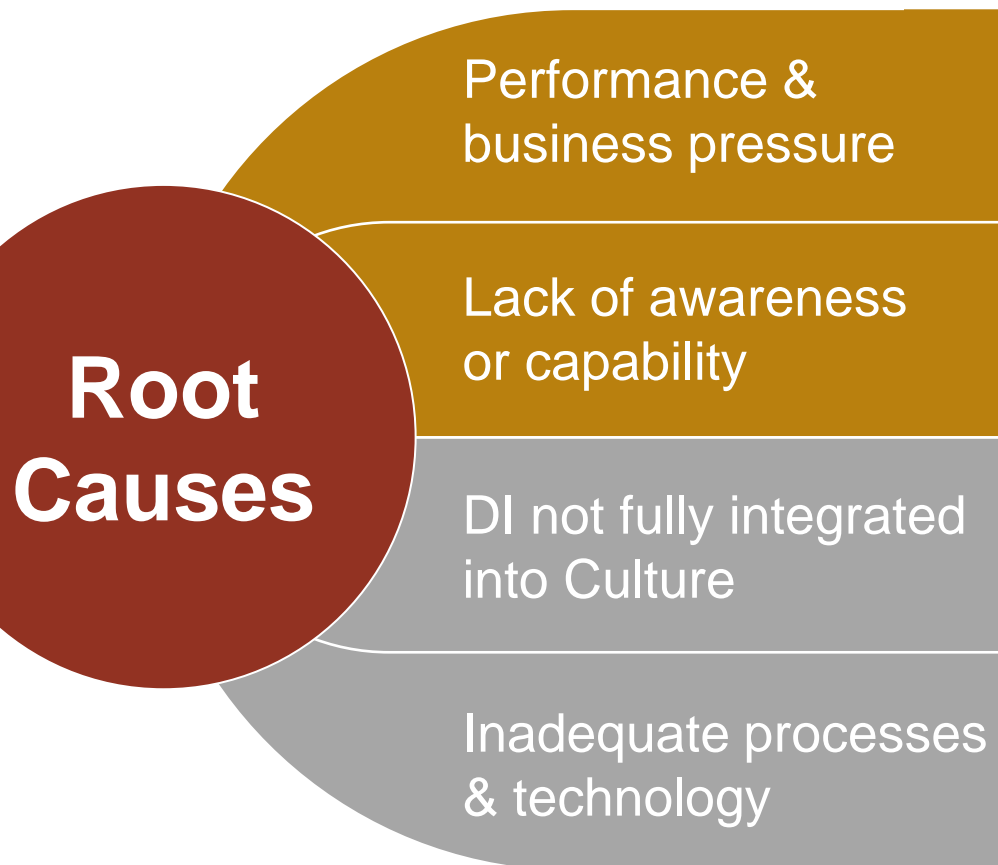
# Why is it so hard for companies to get it right?!



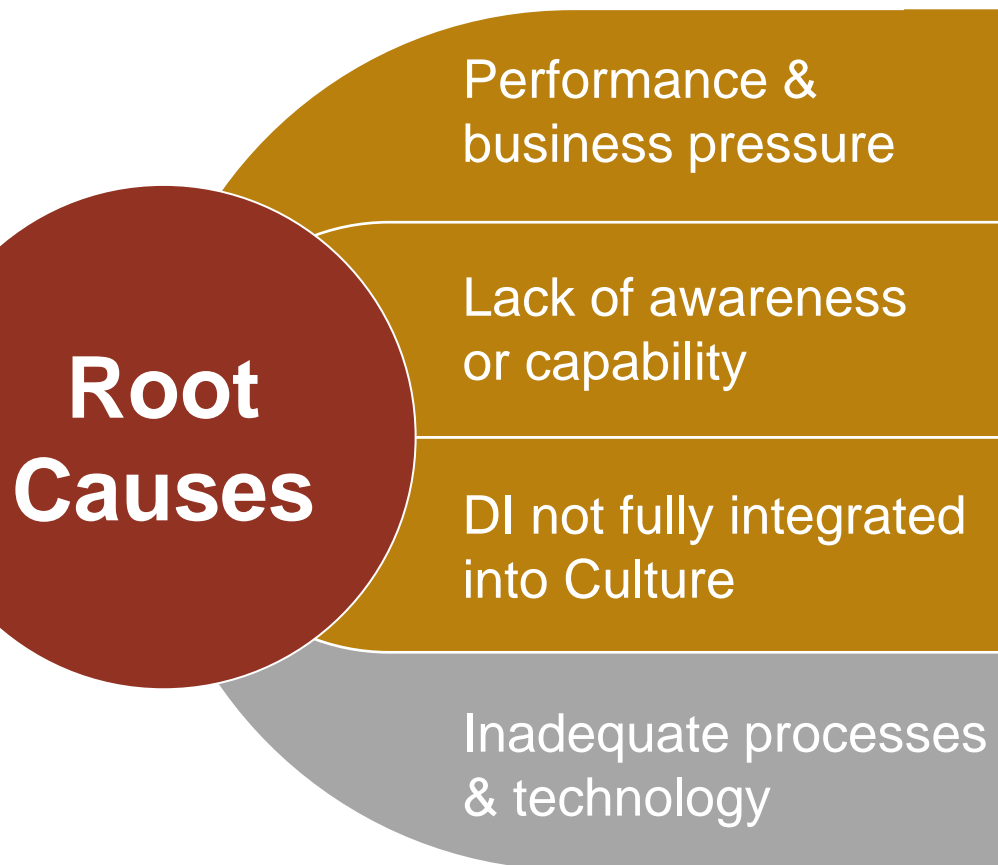
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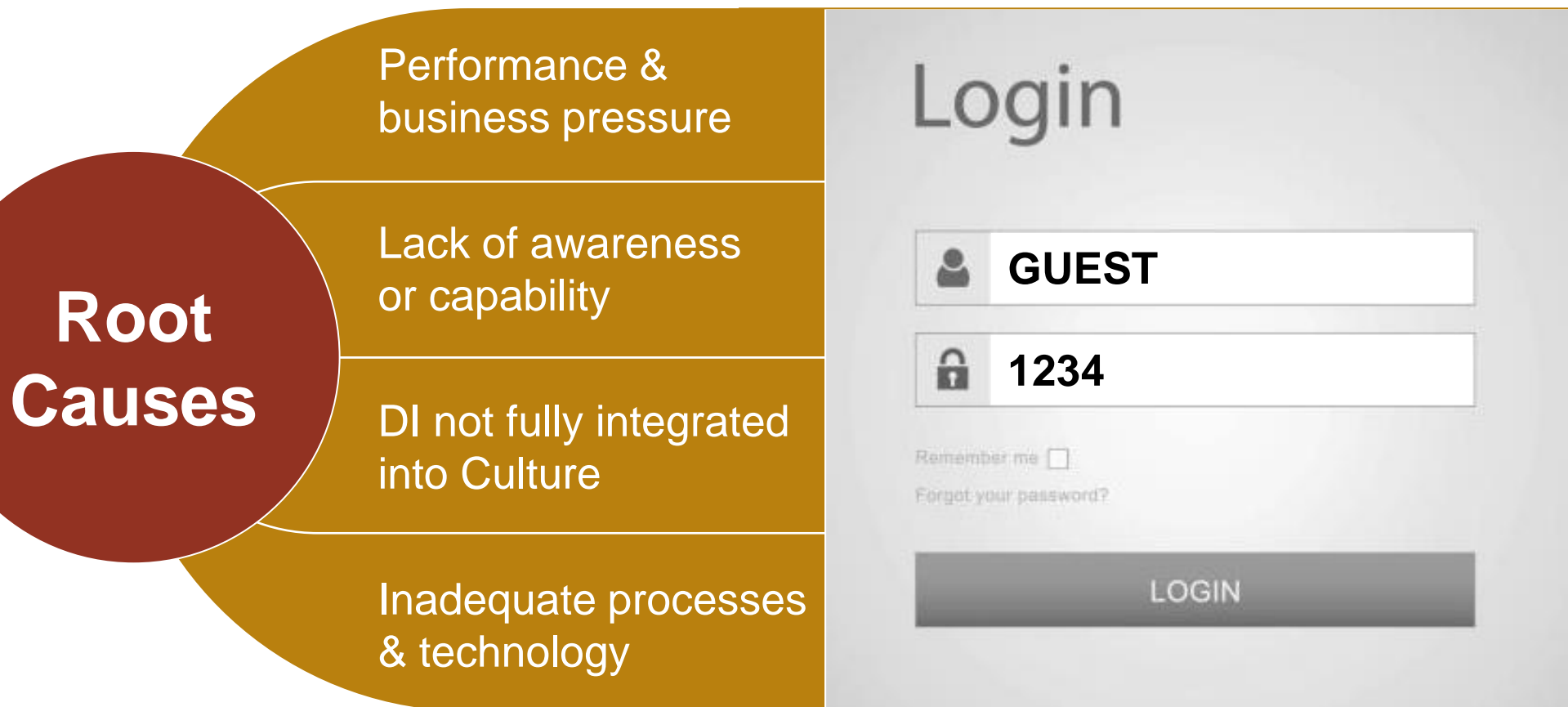


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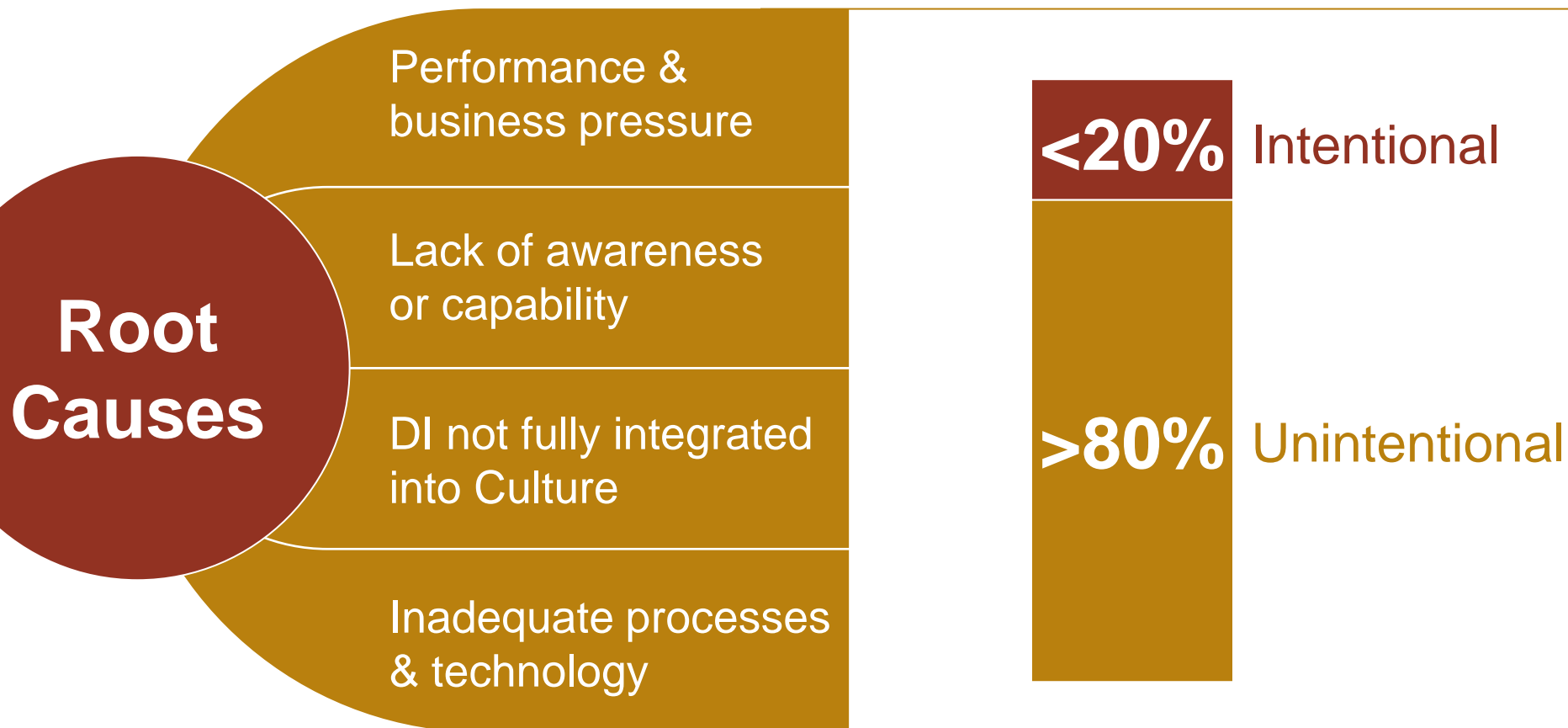




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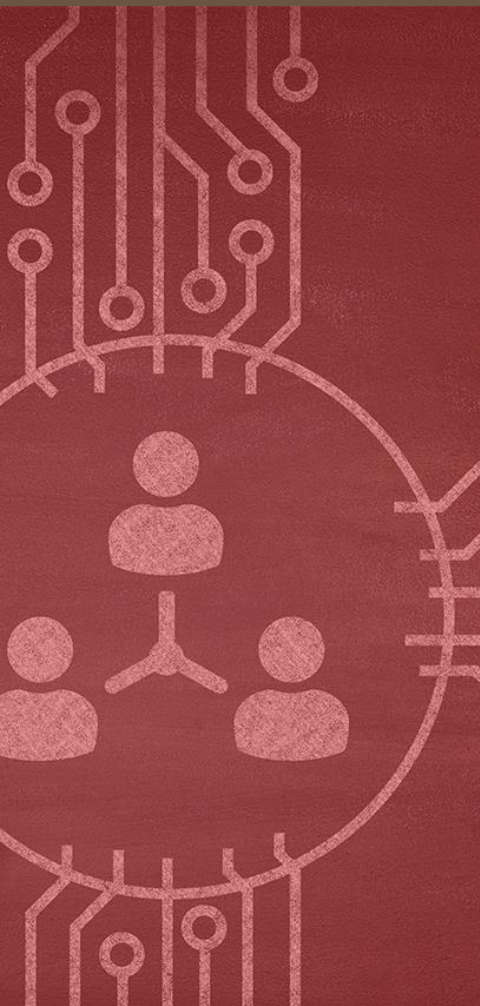


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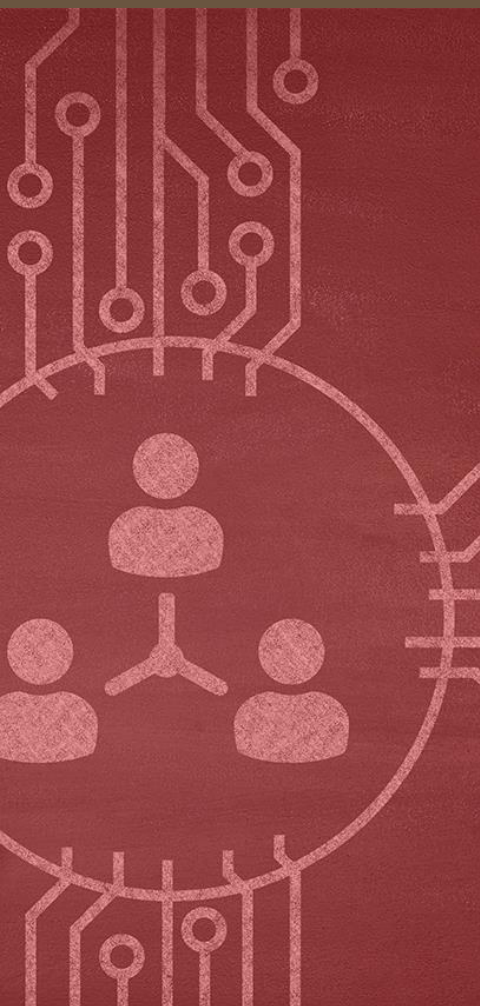
Note: bias based on reporting

# Four vital steps towards Data Integrity



- 1 Education and Communication
- 2 Detection and Mitigation of Risks
- 3 Technology and IT Systems
- 4 Governance of DI

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# What education? What communication?



How to recognize DI issues

**EDUCATE**



DI is everyone's responsibility

**COMMUNICATE**

# Examples of how we're communicating the risks ....and related impact!




**Without data, we don't  
have a product.**  
**Our everyday responsibility.**

Without a product we can't supply our patients.


 **NOVARTIS**


 **Data Integrity**  
Quality Data = Quality Products



**In a hurry?  
Shortcuts compromise quality.**  
**Our everyday responsibility.**

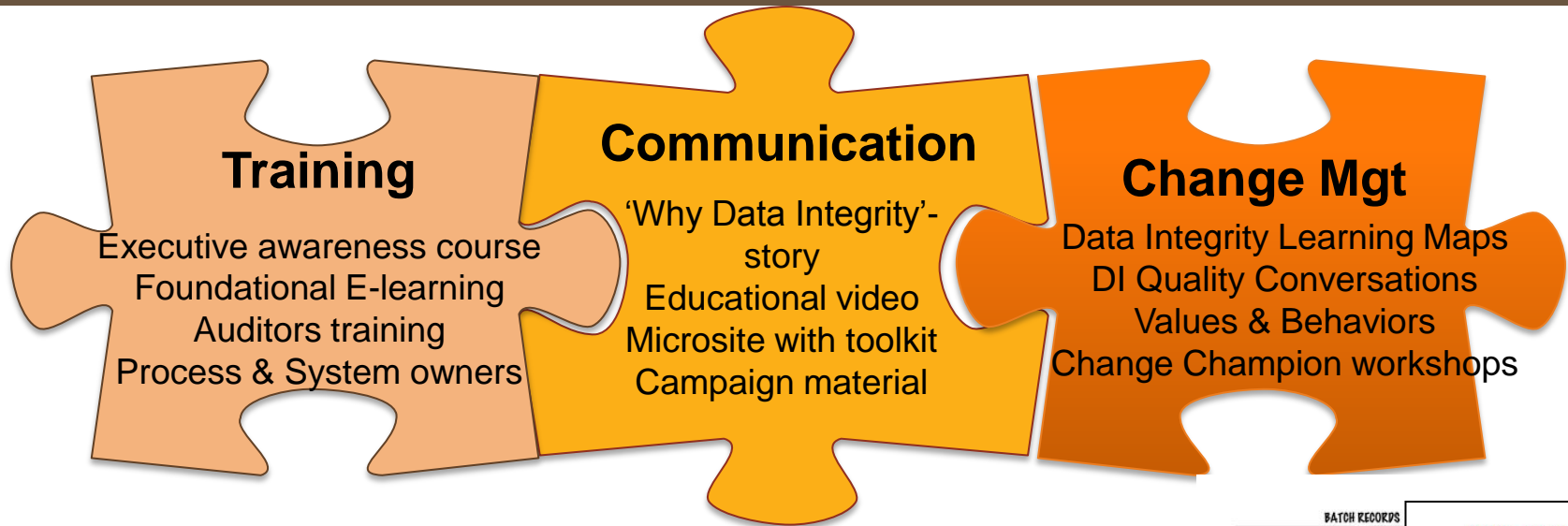
Every procedure is there for a reason.

 **NOVARTIS**

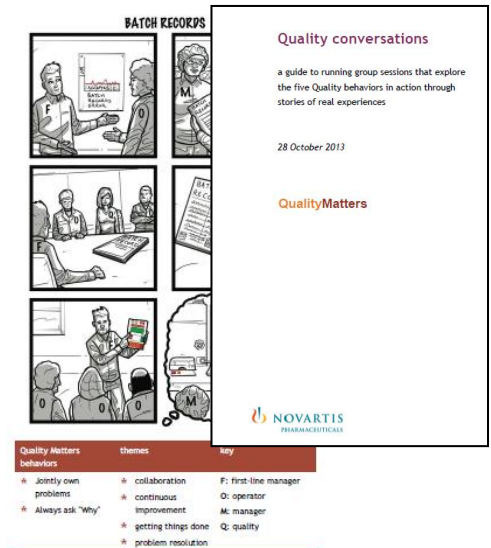
 **Data Integrity**  
Quality Data = Quality Products



# Culture and education is the foundation for a strong Data Integrity mindset



Data Integrity  
microsite



# People are always an element of control.....

....so **mindset shift** to strengthen understanding of Data Integrity and impact on patients safety and product quality are key.

Education and consistent communication ensure:

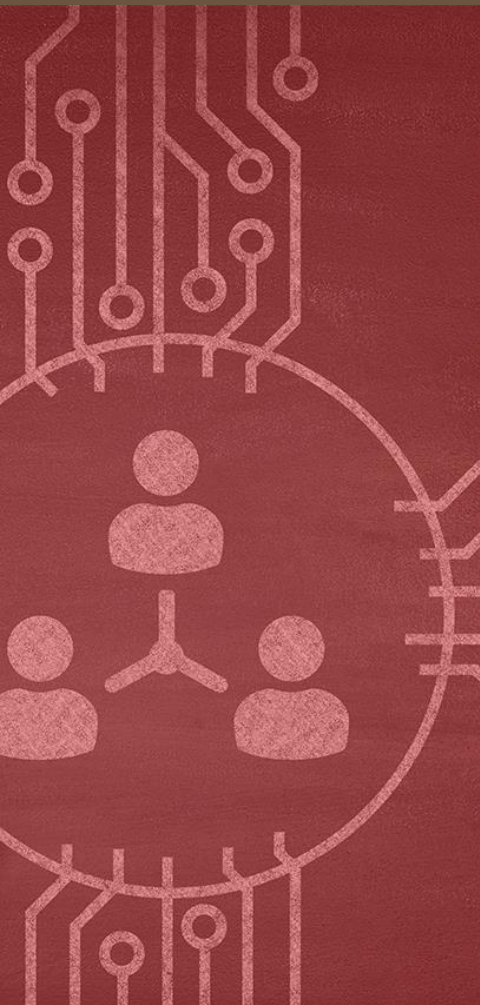
- A common understanding
- Awareness of impact
- Ownership
- Leadership support



**Any further activities can now build on this to ensure sustainability!**



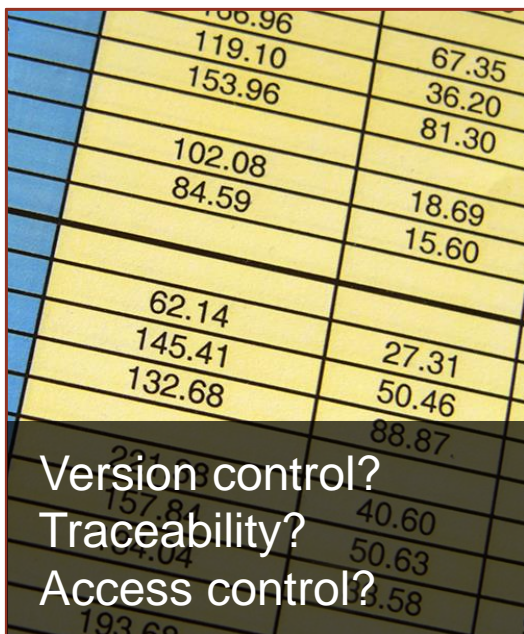
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# Understand risks: known risk areas

## Understand current risks



106.96	67.35
119.10	36.20
153.96	81.30
102.08	18.69
84.59	15.60
62.14	27.31
145.41	50.46
132.68	88.87
221.83	40.60
157.81	50.63
104.04	13.58
193.68	

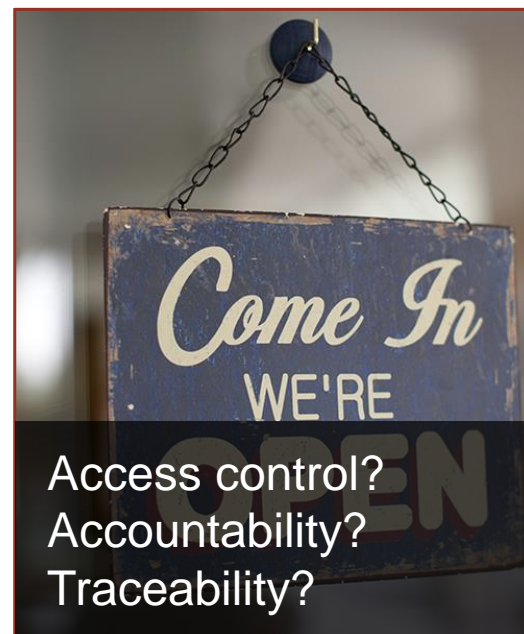
Version control?  
Traceability?  
Access control?

**SPREADSHEETS**



Archiving raw data?  
Audit trail?  
Segregation of duty?

**STAND-ALONE**



Access control?  
Accountability?  
Traceability?

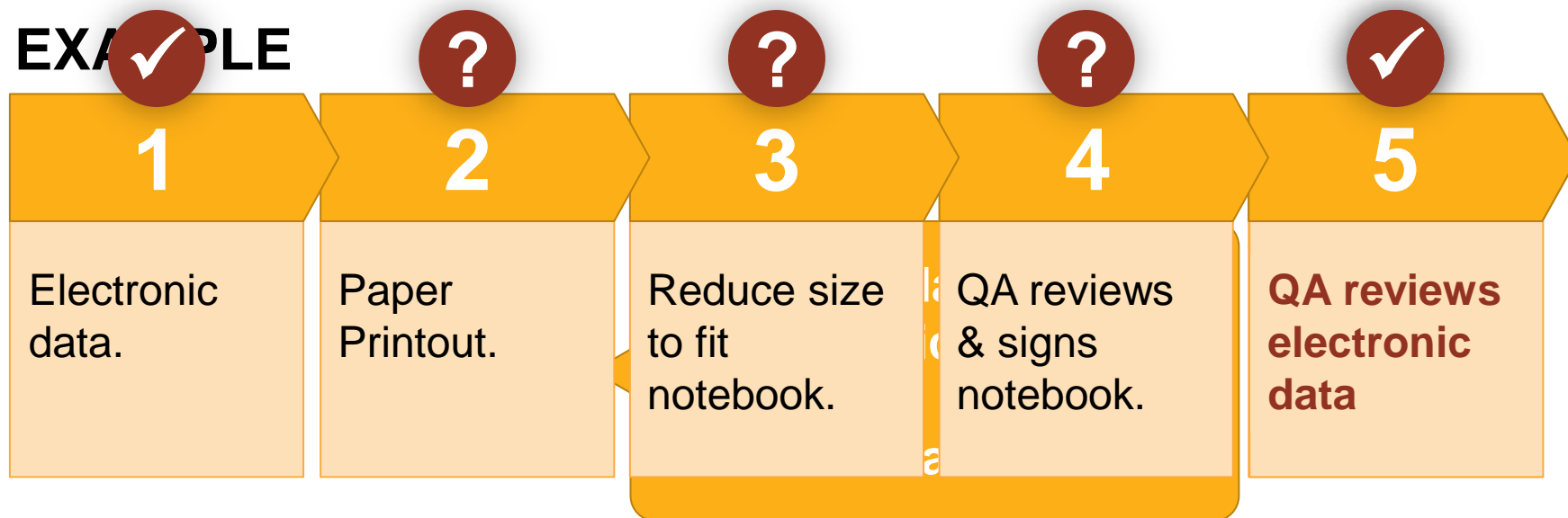
**INSECURE ID**

# DLCPM\*: understand risks, optimize processes

*\*Data Lifecycle Process Mapping*

Mitigate risks

EXAMPLE



# Understand risks through DLCPM\*

*\*Data Lifecycle Process Mapping*

Mitigate risks



Can we review  
original data?

**AVAILABILITY**



Do users (not just IT)  
understand data flow?

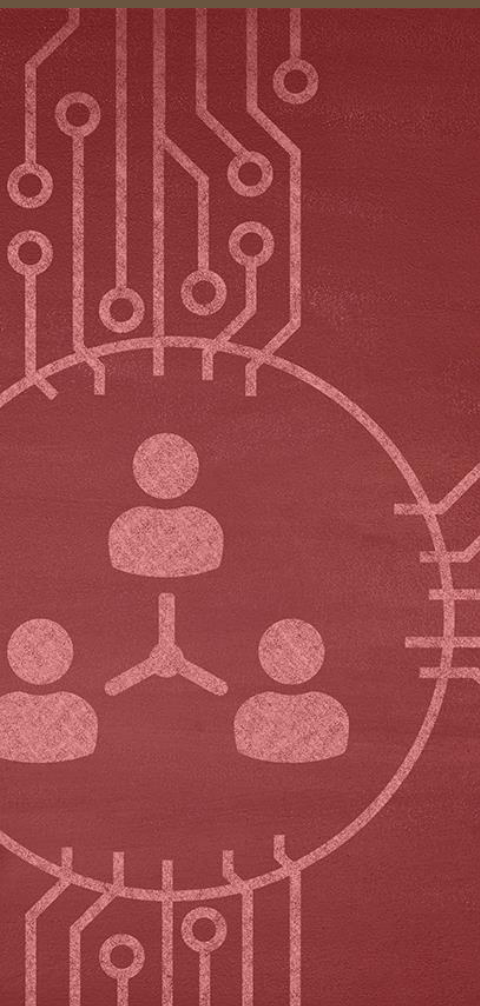
**OWNERSHIP**



Can users change or  
bias results?

**CONTROLS**

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# Processes & systems: prevent risks from emerging

## Mitigate risks

### Define minimum Requirements

#### EXAMPLE

Create explicit requirements for all types of systems, including manual, automated/IT and hybrids.

### Define IT & Process Standards

#### EXAMPLES

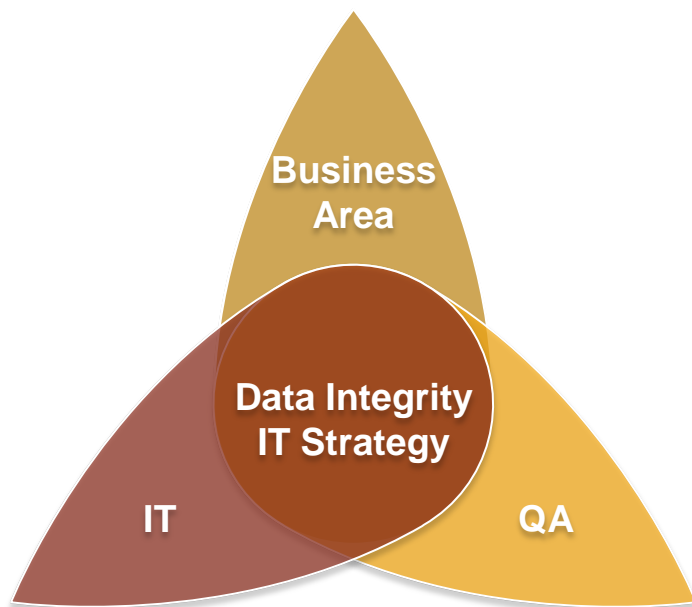
Segregate duties so that those who generate data cannot change it.  
Require data storage & archiving.

### Implement Requirements

#### EXAMPLE

Lock down systems with individual logins, enable audit trails, apply the “Four Eye” principle.

# Define IT and technology strategy

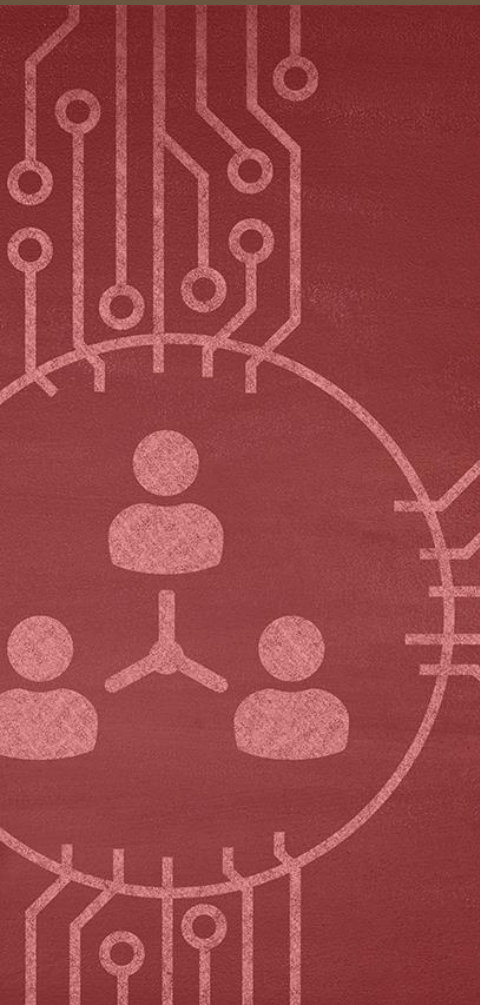


What does our technology landscape vision look like?

How far and fast do we want to move towards our vision?

What are our options?  
What's practical?

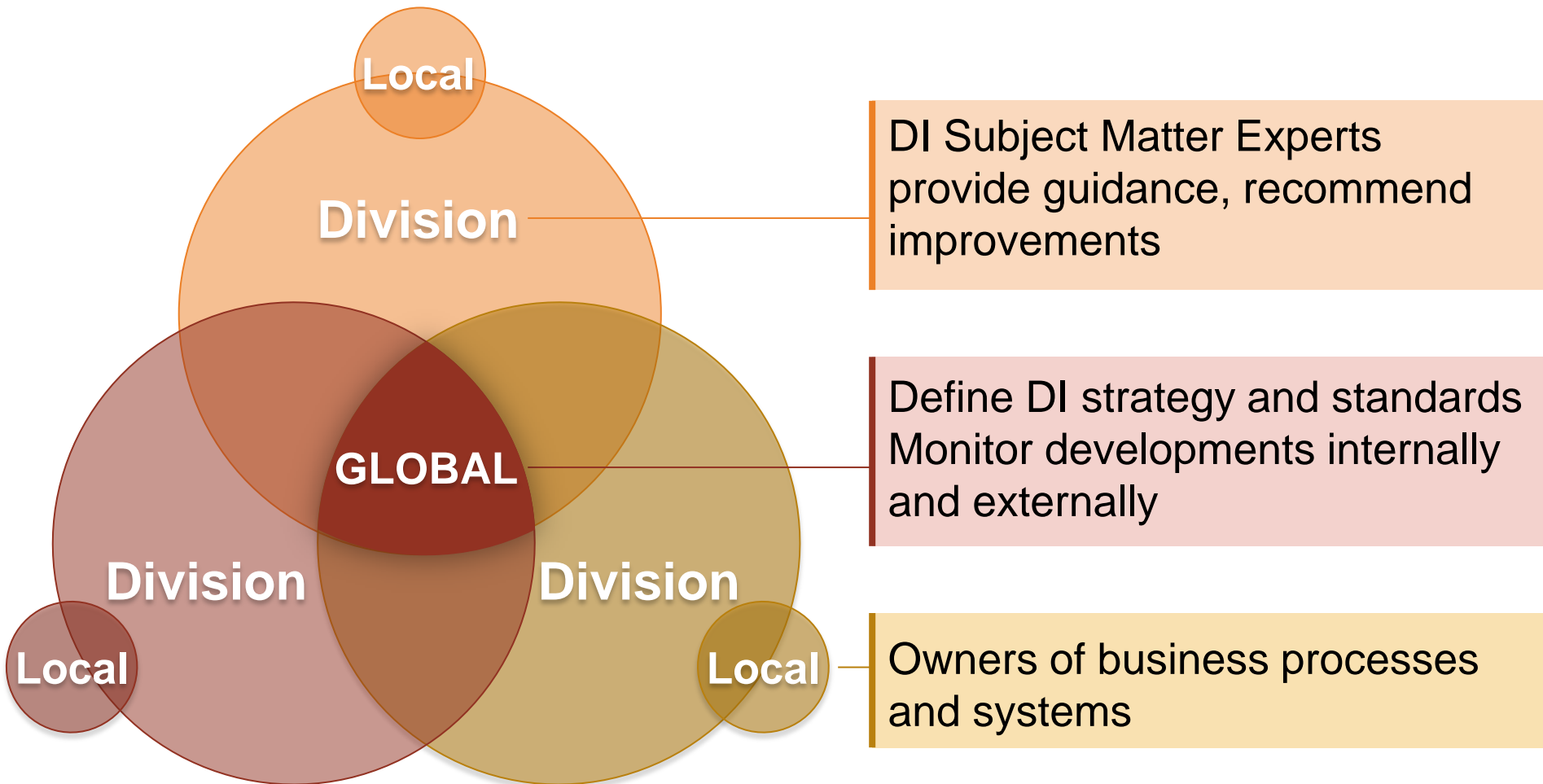
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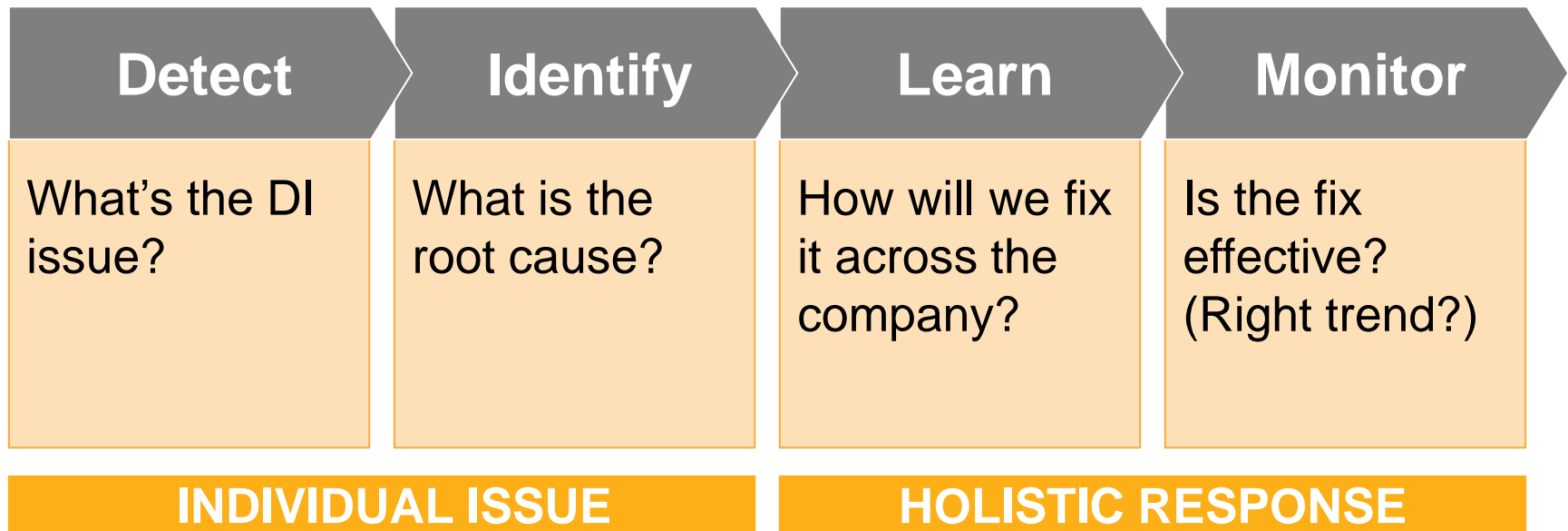
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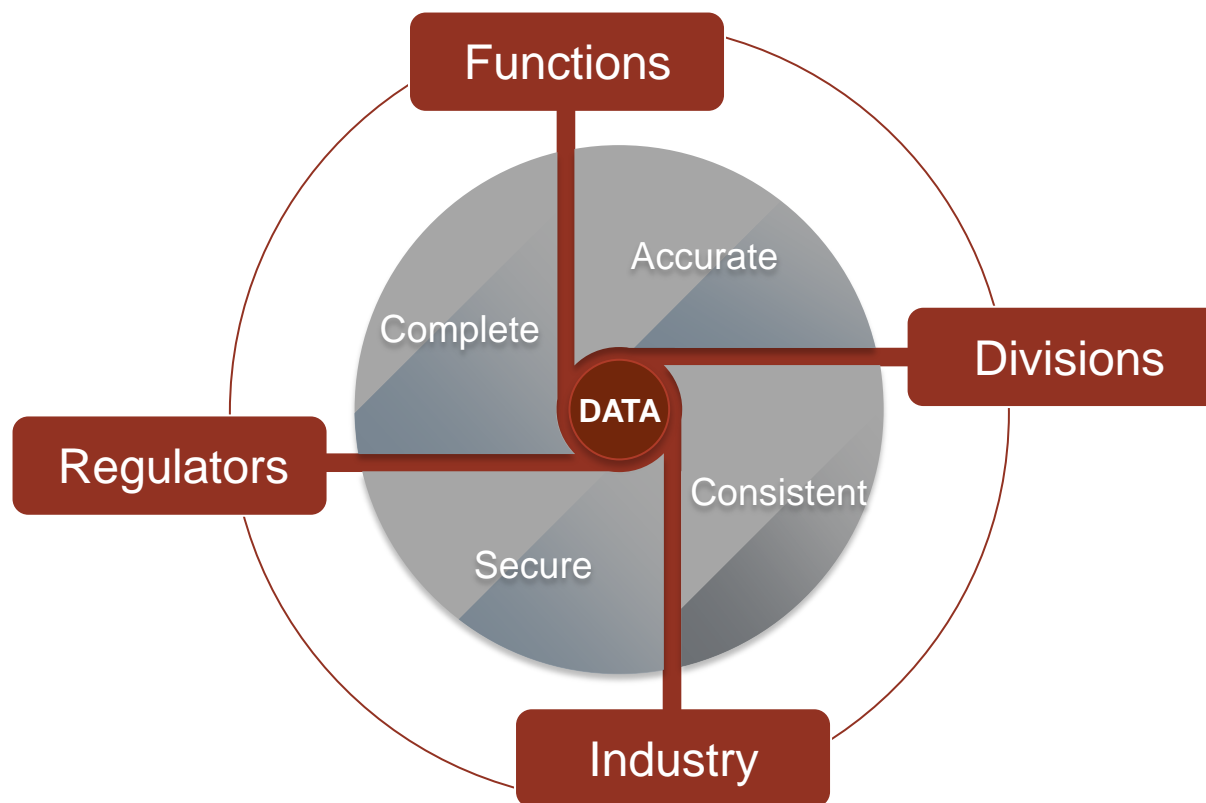
# Establish governance structure



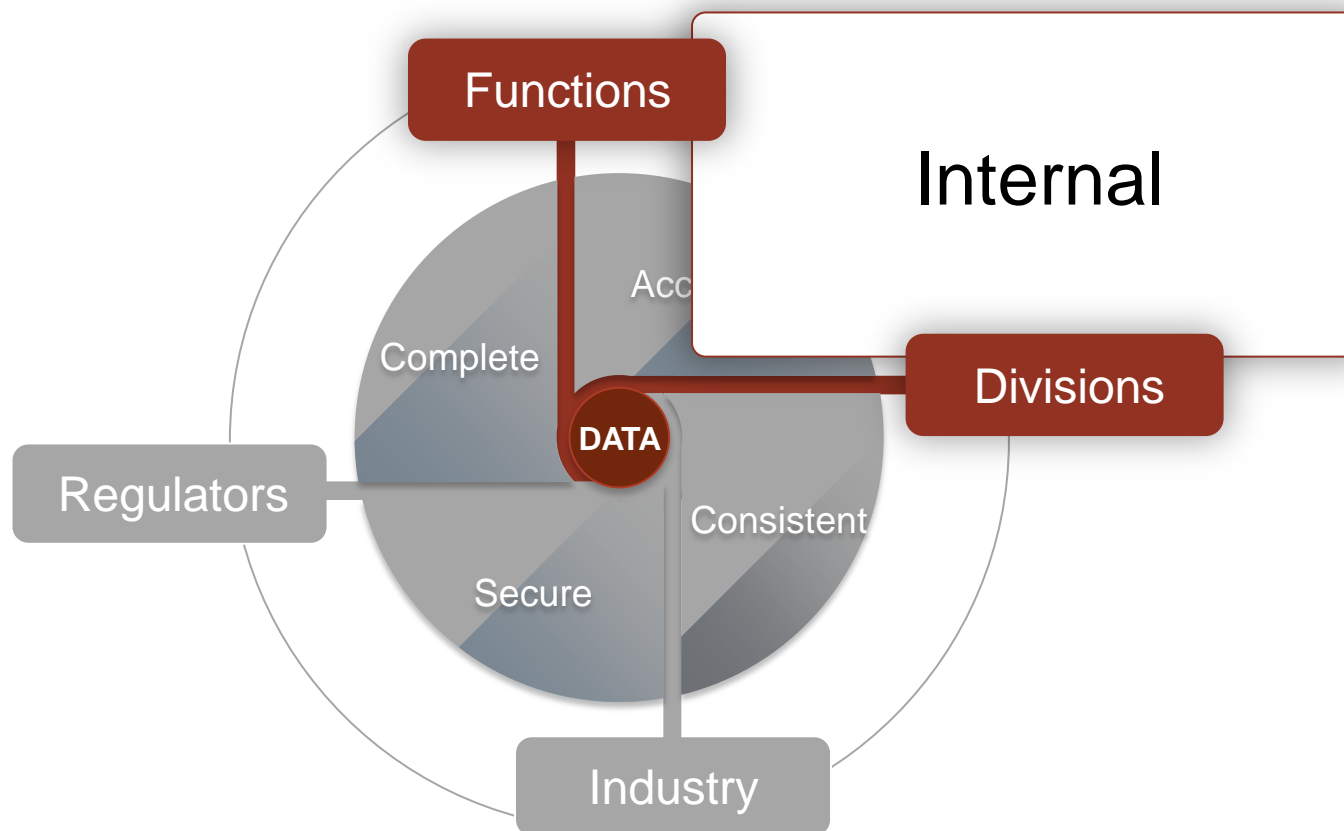
# Establish holistic framework to address DI issues



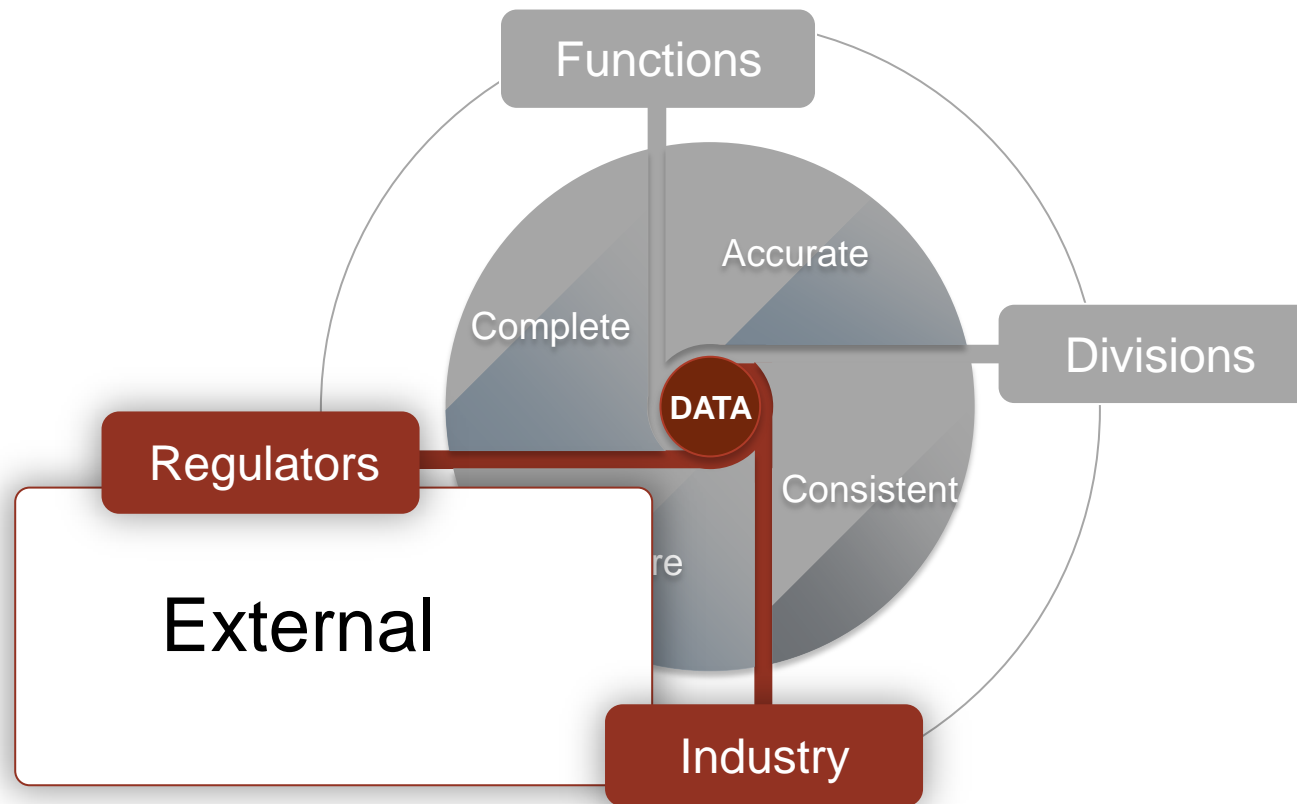
# Collaborate to leverage lessons learned



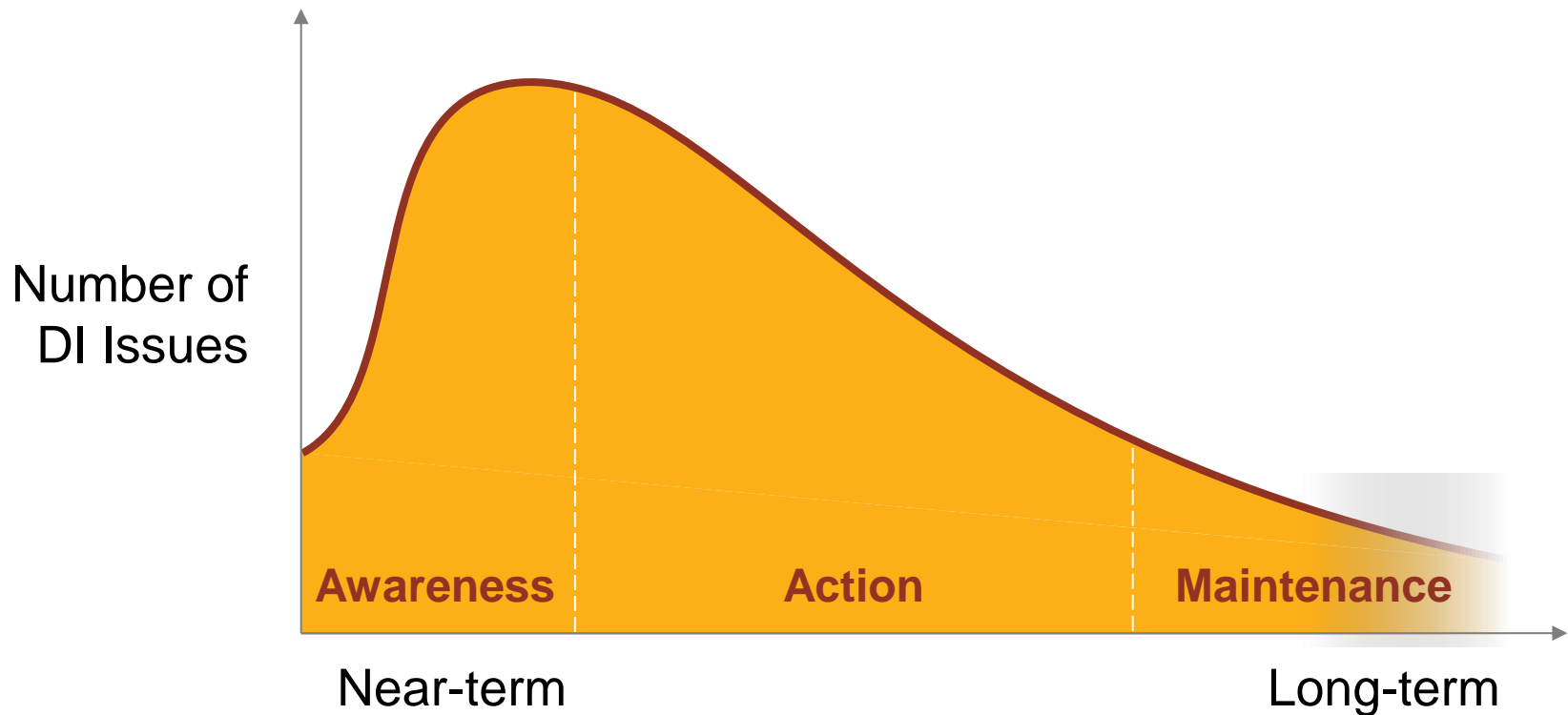
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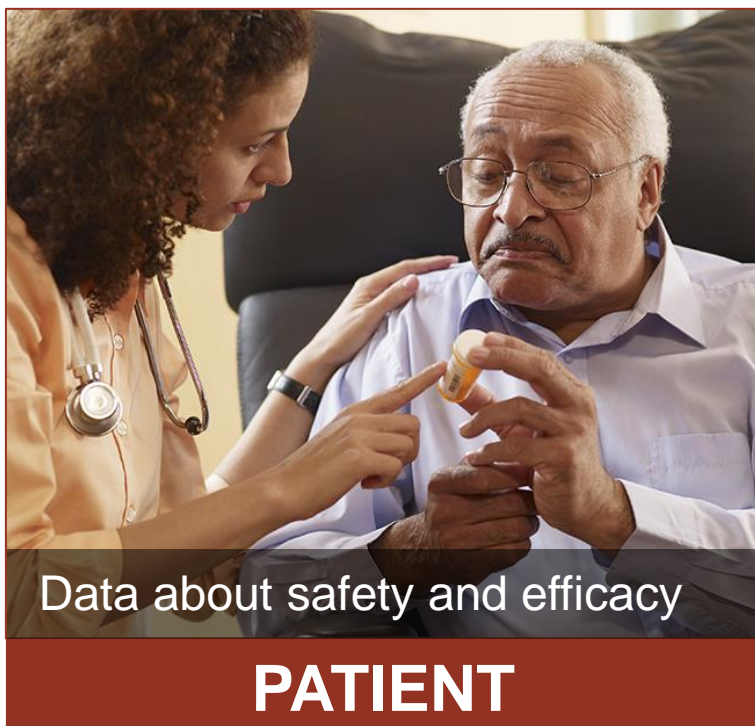
# Learn lessons from the industry and regulators



# As awareness rises, we'll see more issues at first



# Priorities: patient and product quality



# Discussion

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- How are you prioritizing your DI initiative / activities?
- Where have you chosen to start? Why?