

Applying Technologies Across the End-to-End PV Process to Increase Compliance and Quality

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Safe Harbor Statement

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Agenda

- Industry Dynamics
 - What does the evolving PV landscape look like? What are the challenges we face?
 - Quality: what form does it take and how does it change across product portfolios?
 - Breaking down the PV business processes
- Applying Technologies for Better Compliance and Quality
 - Use industry standards
 - Maximize the quality of case data intake
 - Automate the case processing steps
 - Track operational metrics
 - In aggregate reporting, separate the logic layer from the presentation layer
 - Standardize the signal review and surveillance process

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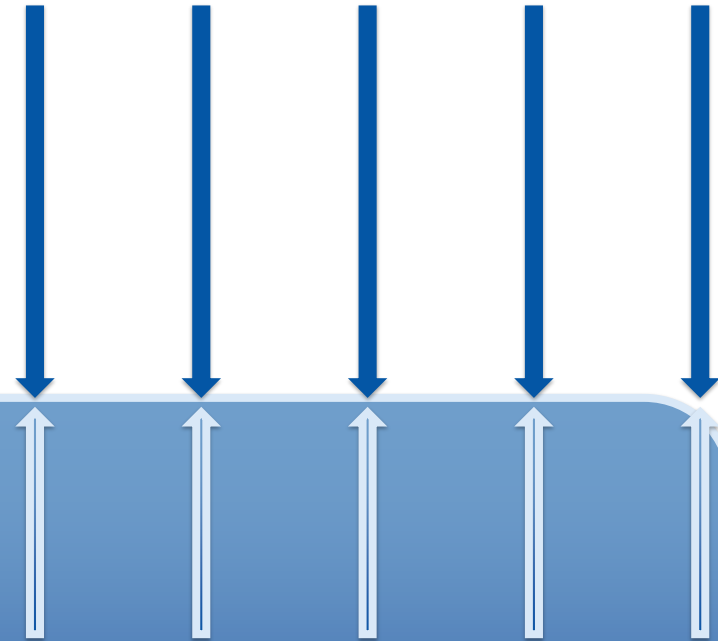
What does the evolving PV landscape look like? What are the challenges we face?

External forces

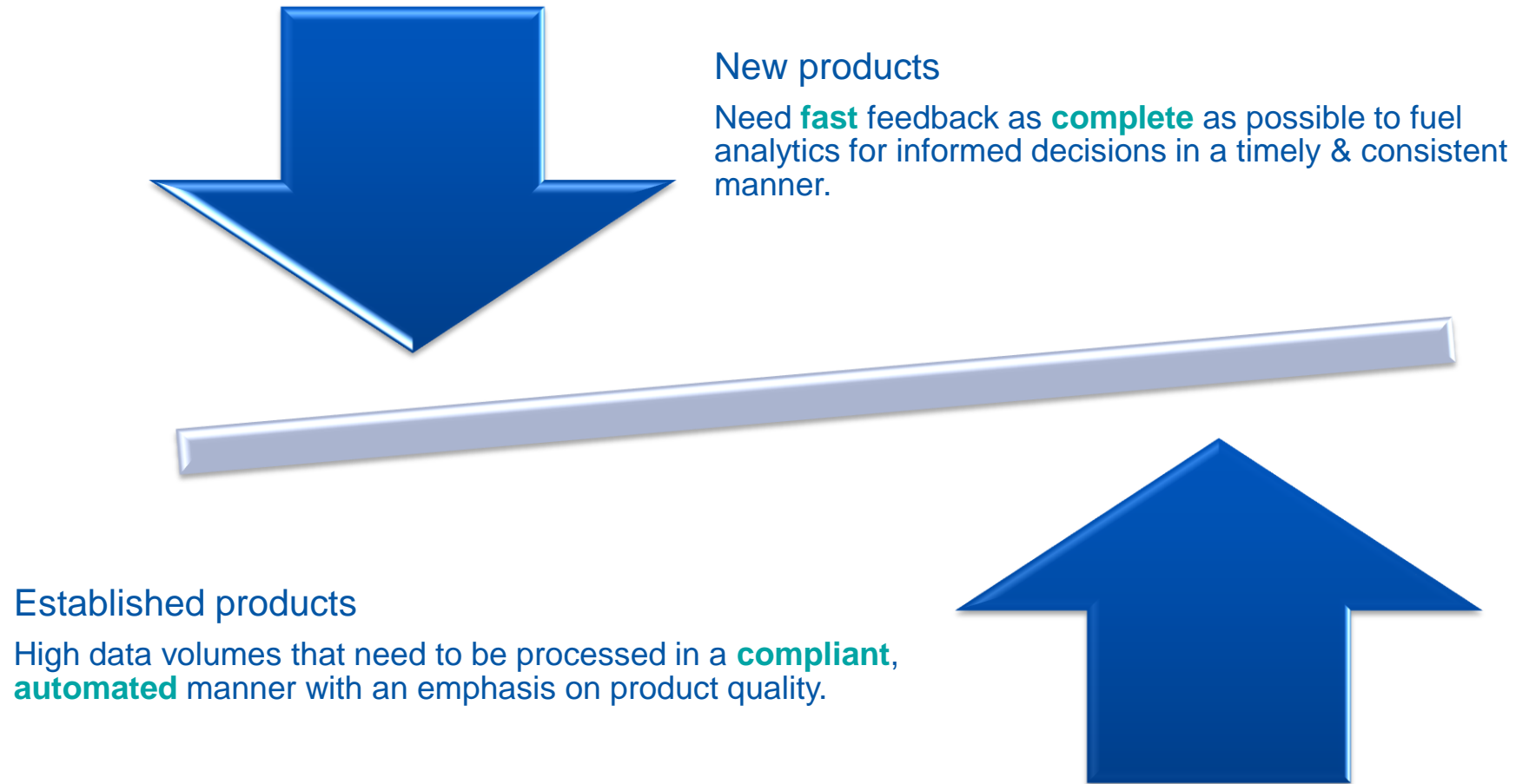
- Growing consumer awareness & advocacy
- Increasing PV regulation
- Increasing inspection scrutiny on non core areas
 - Affiliate practices
 - Patient Support Programs
 - Sales Rep activities

Internal forces

- Aggressive annual growth of cases reported
- Cost containment pressure
- Varied portfolios with differing demands

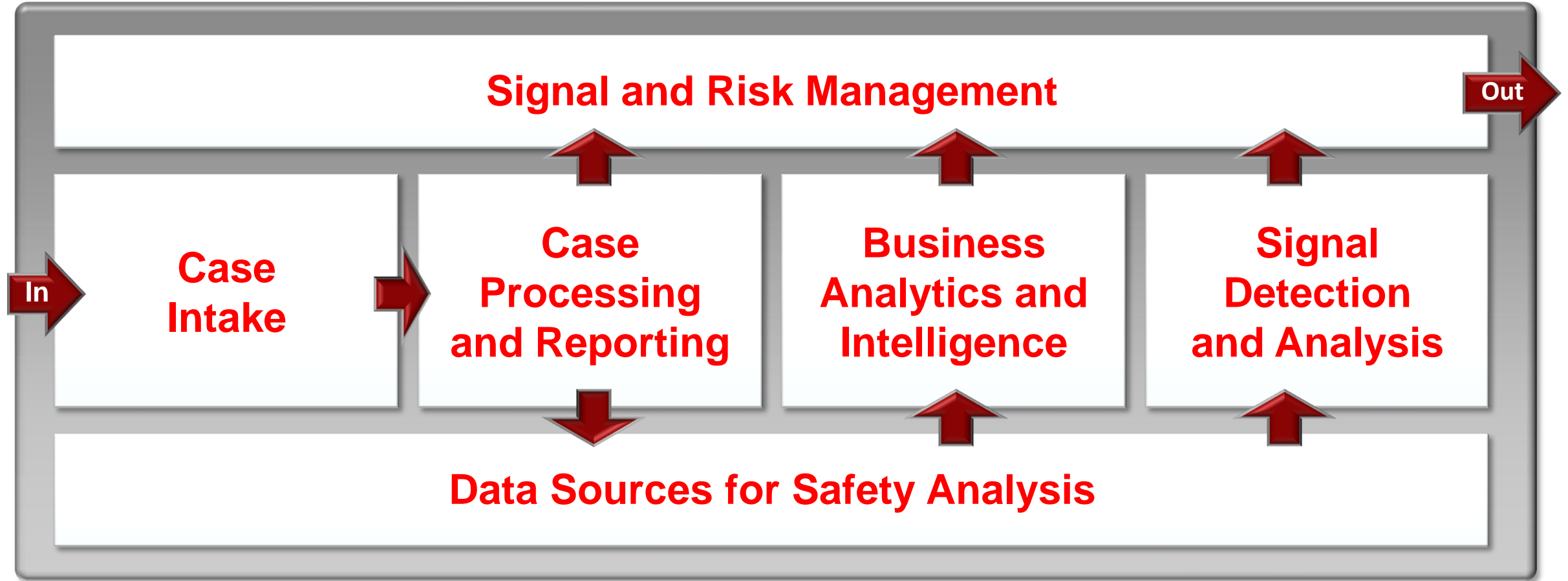


Quality: What form does it take and how does it change across product portfolios?



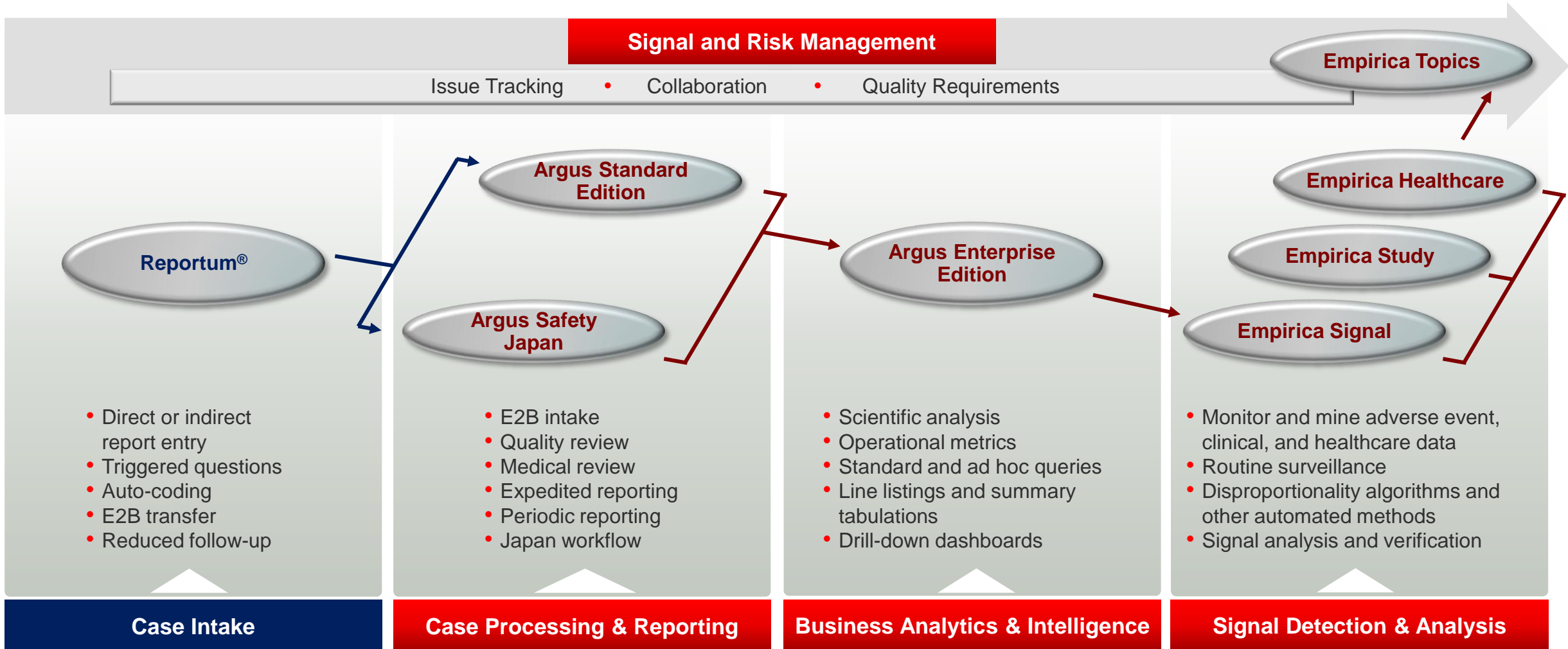
Product Safety and Pharmacovigilance

High-Level Business Processes Supported by Disparate Data



Oracle Health Sciences Safety Suite + MyMeds&Me Reportum®

Integrated Solution Supporting the End-to-End Pharmacovigilance Process



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Driving to Better Standards

E2B(R3), eVAERS, eMDR and IDMP

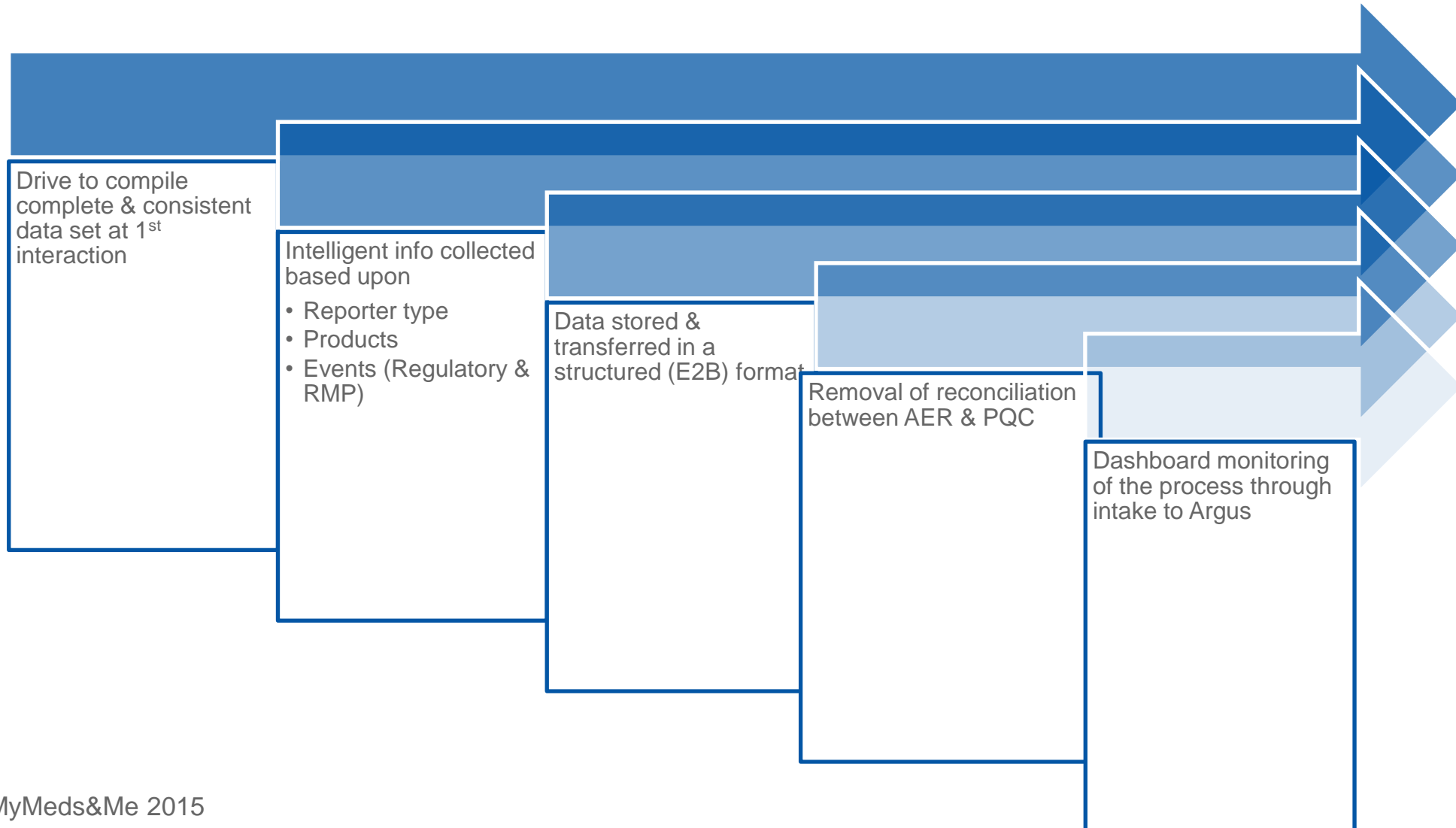


- New standards adapted to the needs of regulators and industry
- Better interoperability and robustness
- More modern IT standards that fix issues with E2B(R2)
- Merges elements of the healthcare standard HL7
- Allows collection of additional safety information, which translates to safer products for patients

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Quality across the portfolio – Into the detail...

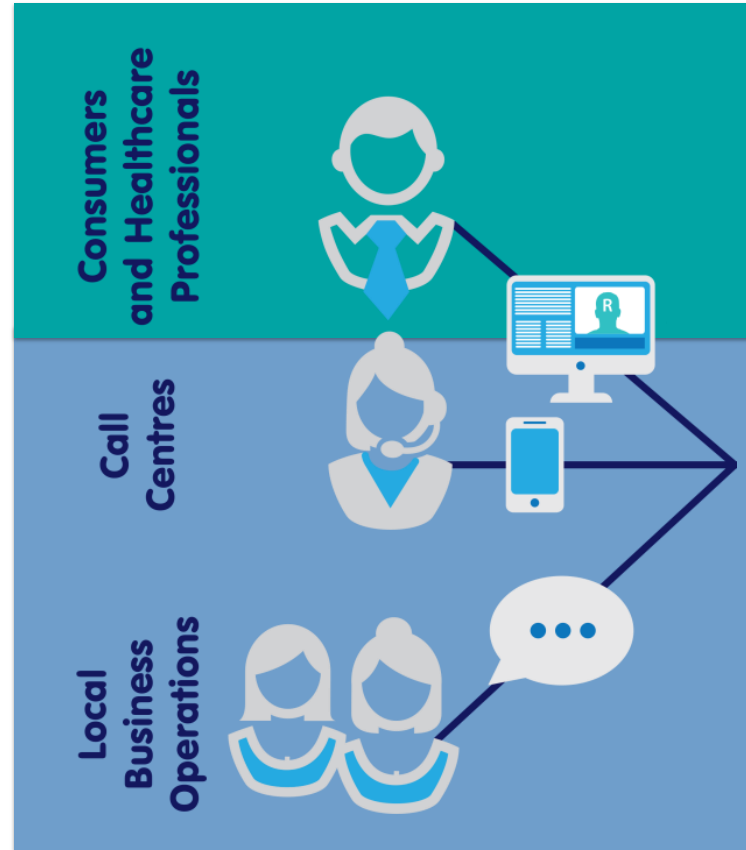


How does technology influence this?

End user experience & effectiveness

Direct Reporting
Spontaneous AER
Patient Support
Programs

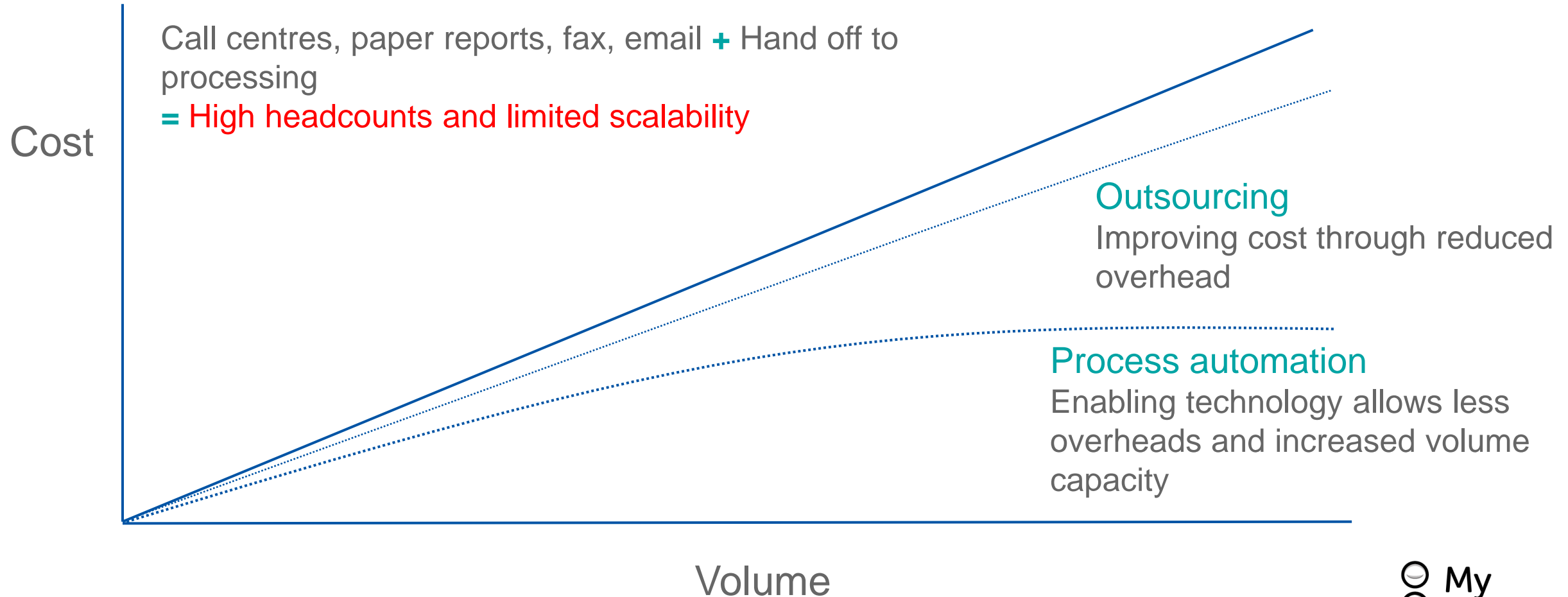
Indirect Reporting
Via Companies



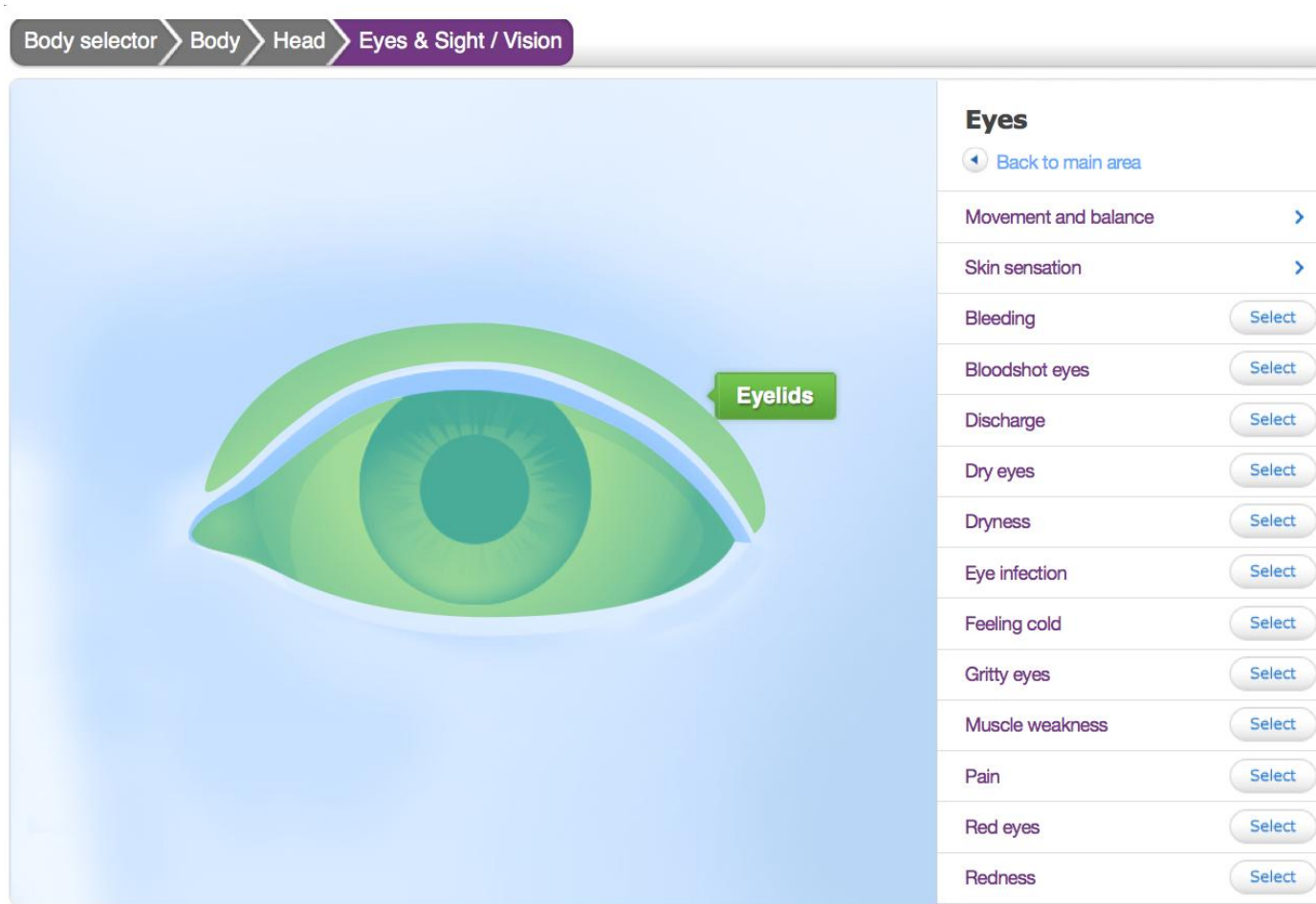
- Logical questioning, in stream enables the reporter to give maximum relevant info
- Background medical history and con meds
- Event questions dependent upon responses provided
- Product & event specific question triggers
- Product identifiers

How does technology influence this?


Internal value & efficiency



Intuitive, intelligent technology at its best



Intuitive, intelligent technology at its best



Mmm Pharma Reporting Home MMM.com Contact Us (john.operator@pharma.com) Logout

MMM Pharma

Side Effects > Contact Details > What Happened > Medicines > **Other Conditions** > Investigations > Summary > Confirmation

Report reference: QCLY5ET1 Version: 1 Your session will time out in 13:37 Cancel & Return to Homepage

MMMPharmaject is a combination product - Check for Product Complaint

Other Conditions

Please indicate if the patient has any of the following risk factors? Please tick all that apply

<input type="radio"/> Biliary non-obstructive	<input type="radio"/> Biliary obstructive disease
<input type="radio"/> Congestive cardiac failure	<input type="radio"/> Diabetes
<input type="radio"/> Dyslipidemia	<input type="radio"/> Exposure to toxic agent
<input type="radio"/> Fatty liver or steatohepatitis	<input type="radio"/> Haemodynamic shock
<input type="radio"/> Hepatitis history (including A, B, C, D and E)	<input type="radio"/> History of alcohol abuse
<input type="radio"/> Inborn error of bilirubin metabolism	<input type="radio"/> Intravenous drug abuse
<input type="radio"/> Malignancy	<input type="radio"/> Obesity
<input type="radio"/> Recent blood product transfusion	<input type="radio"/> Recent exposure to blood products or body fluids
<input type="radio"/> Recent travel to foreign country	

Are there any other medical conditions that we should know about?

Add other condition

Intuitive, intelligent technology at its best

 MyMeds&Me. [Home](#) 新しいレポートをログに記録 Log a New Report

報告書の種類

何を報告しますか？

☐ 有害事象 ☐ 製品クレーム ☐ 医療情報のリクエスト

会社が有害事象を認識した日

2015-10-27

製品

製品名

ここに入力すると提案が表示されます...

製品の使用開始日

2015-10-27

報告者の詳細

名 姓

報告者のその他の情報はありますか？

☒ いいえ ☐ はい

Submit

Case Study – US Market Reports

Goal of Reportum® adoption: Improve the quality of data captured whilst streamlining and standardizing report capture

Deployment Overview

- Live for 1yr +
- High Volumes (70,000 reports p.a. +)
- Collection of PQC & MI requests in addition to AEs
- Reportum workflow allows data to be QC'ed within Reportum before the data moves to Oracle Argus

Benefit

- Clear metrics illustrating the streamlining of effort in processing report intake
- Automated E2B transfer in place

Conclusion

For intake: Quality of data increased, time per report decreased. Manual effort for Argus entry reduced.

Reportum[®] and Oracle Argus

- E2B
 - R2 & the potential to extend
 - R3 capabilities, e.g. attachments
- Coding
 - MedDRA & synonyms
 - Product coding
- Product quality information & tracking

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Automating Case Processing Steps

- Auto-intake
- Auto-triage
- Auto-coding
- Auto-scheduling/generation/submission
- Auto-archiving

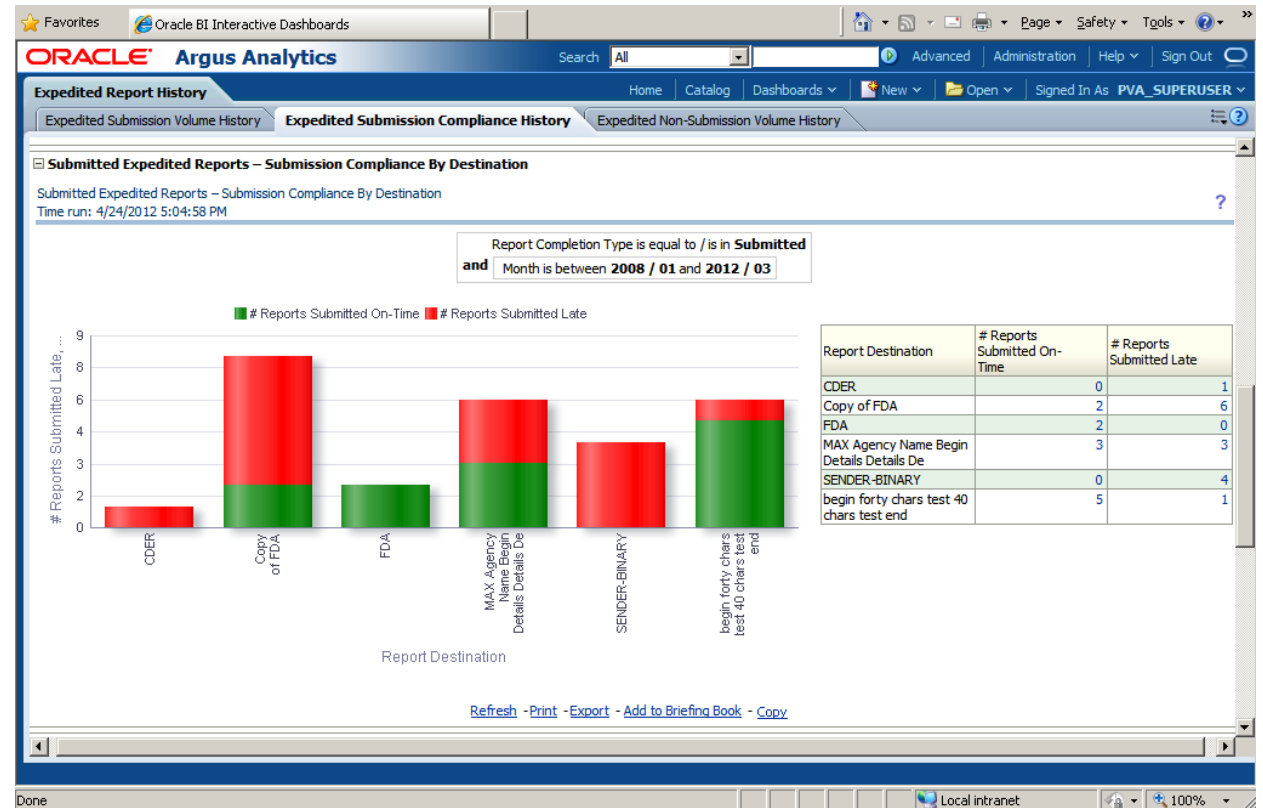


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Tracking Operational Metrics

- Compliance throughout case processing
- Current and retrospective metrics
- Idle time analysis
- Case rework analysis



Compliance Throughout Case Processing

Workflow Steps

Complete each workflow step within internal deadlines in order to lock cases on time (workflow step compliance)

Case Lock

Lock each case within internal deadlines in order to leave sufficient time to submit expedited reports (lock compliance)

Report Submission

Submit each expedited report within regulatory deadlines (submission compliance)

Current and Retrospective Metrics

Measure work in process



**Workflow
Steps**

**Case
Lock**

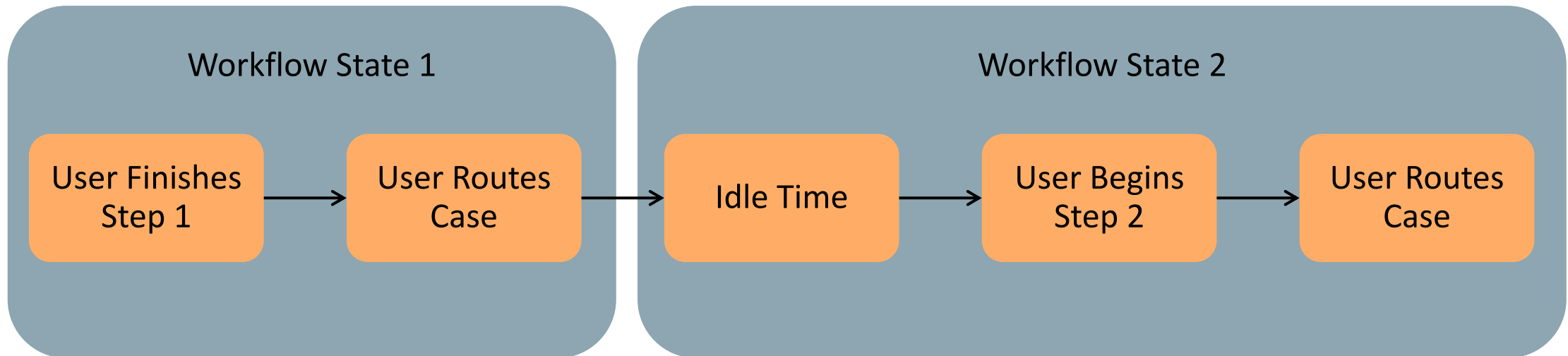
**Report
Submission**

Measure completed work



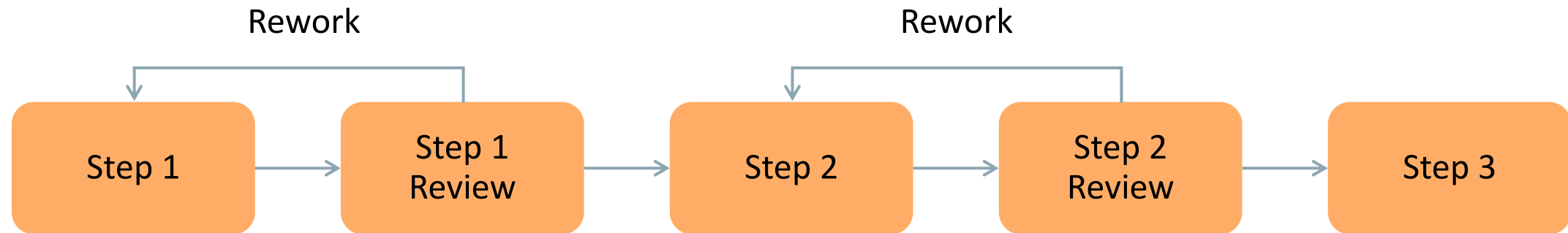
Idle Time Analysis

- Analyze the time that cases sit in workflow states before being picked up and worked on
- Optimize the business process to reduce idle time



Case Rework Analysis

- Analyze rework being done due to unsatisfactory quality
- Take corrective actions such as training to reduce future risk



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Separating the Logic Layer from the Presentation Layer

- 1 Data consistency
- 2 Report reusability
- 3 Report performance

Data Consistency



- Traditionally reports have the logic built-in, so report writers create their own logic (according to their own interpretations) during report creation; this inevitably leads to inconsistencies across the organization (different reports give different answers)
- Having the logic layer separate from the presentation layer helps keep it under control – one source of truth

Report Reusability



- Traditionally you need many reports and they are expensive to develop because they include the case selection logic
- In the Oracle platform, queries are used to select the cases (logic layer) while the reports are separate (presentation layer)
- This means reports are reusable for many purposes, which reduces dramatically:
 - the number of reports that needs to be developed
 - the cost per report

Report Performance

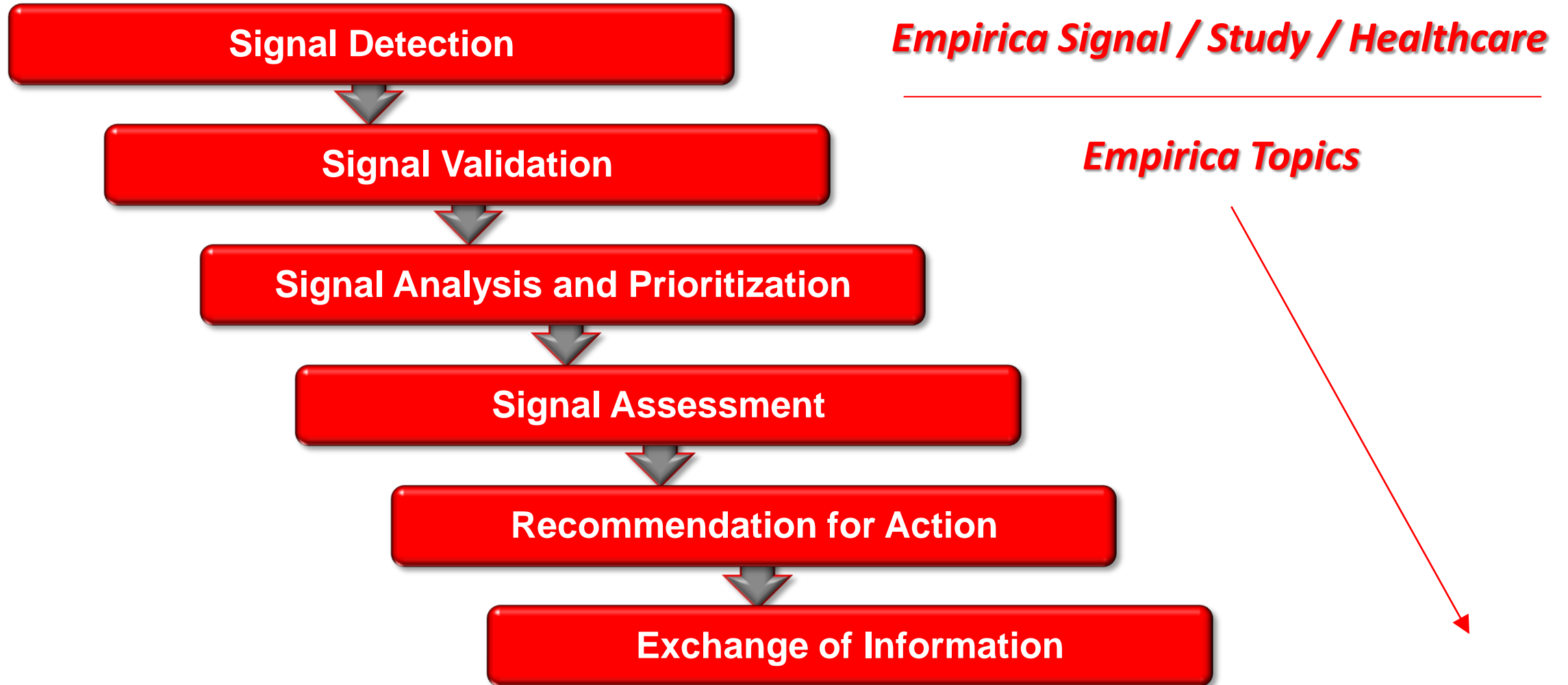
- Queries create a case series, a small subset of the data mart
- The report is executed against this case series, after the safety evaluator has made any necessary changes
- This means much better performance than running a report against the entire data mart




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The Signal Management Process



Routine Surveillance


Drug-Event Combinations

[Preferences](#)
[Settings](#)
[Feedback](#)
[Exit](#)
[Help](#)

[Home](#)
[Drugs](#)
[Data Mining Runs](#)
[Data Mining Results](#)
[Queries](#)
[Case Series](#)
[Reports](#)
[Signals](#)
[Topics](#)









User: Robert Weber [admin.weber], View: Pediatric alert*
 [Drug Overviews](#)
[Drug-Event Combinations](#)
[Drug Comments](#)

Group: Reviewer: Drug: SOC:


[Select View](#)
[Filter By Comments](#)
[Save As View](#)
[Manage Views](#)

[Columns and Rows](#)
[Print](#)
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[Select Rows](#)

AERS Signal Configuration Rows are filtered
 19 rows Sorted by Pediatric Alert, SOC, Pediatric EB05 2013Q1 desc
 Rows Per Page: Page of 1


	Drug	SOC	Event	Pediatric	Pediatric	Pediatric	Pediatric	Adult	Comment	Topic	Topic
				Alert	Nsince 2012Q4	N 2013Q1	EB05 2013Q1	EB95 2013Q1		Name	State
	Ibuprofen	Musc	Juvenile idiopathic arthritis	**NEW**	1	27	2.155	1.967			
	Ibuprofen	Renal	Renal failure acute	**NEW**	4	240	3.548	2.538	Bring to Meeting	Ibuprofen - Pediatric ...	1 - Create
	Ibuprofen	Resp	Throat irritation	**NEW**	3	282	4.926	2.471			
	Ibuprofen	SMQ	Oropharyngeal conditions (excl neoplasms, infections and allergies) (SMQ) [narrow]	**NEW**	22	1373	3.017	1.542			
	Ibuprofen	SMQ	Oropharyngeal disorders (SMQ) [narrow]	**NEW**	28	1631	2.736	1.509			
	Ibuprofen	SMQ	Acute renal failure (SMQ) [narrow]	**NEW**	8	451	2.127	1.696	Bring to Meeting	Ibuprofen - Pediatric ...	1 - Create
	Ibuprofen	Skin	Toxic epidermal necrolysis	**NEW**	7	76	2.458	2.059			
	Ibuprofen	Skin	Swelling face	**NEW**	5	83	2.442	2.162			

Building a Risk Knowledgebase

 **Topic** [Home](#) [Data Mining Runs](#) [Data Mining Results](#) [Queries](#) [Case Series](#) [Reports](#) [Signals](#) [Topics](#)

User: Sara Evans [sara.evans], Topic: Pediatric antidepressants - Suicidality

[Print](#) [Show All](#) [Hide All](#) [Back](#)

 **Topic General Information**

Visible to work teams:

Antibiotics

Antidepressants

[Browse](#)

Topic name*:

Pediatric antidepressants - Suicidality

Topic description:

Pediatric antidepressant use - Suicidal thoughts and behavior

Current state:

Assigned

Reason for change*:

Assigned to user*:

Mark Oneil [mark.oneil]

Keywords:

Pediatric suicidality


☒ Add to existing project:


Unassigned


☐ Add to new project named:

Save

Cancel

 **Topic Links**

 **Topic Comments**



 **Topic Attachments**

[Add Topic Attachment](#)

[Columns](#) [Print](#) [Download](#)

2 rows

Rows Per Page: 50Page 1 of 1

	Attachment name	Attachment description	Source	Created By	Comments
	Docket for 2004 FDA Proceedings	This document analyzes and evaluates data submitted by sponsors of several psychotropic drugs in response to FDA requests regarding data pertinent to pediatric suicidality.	URL	Mark Oneil	0
	FDA black box warning letter	FDA letter requesting a labeling change for antidepressants to include a black box warning about suicidality in children and adolescents	File	Sara Evans	0



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Simplifying adverse event reporting
and product quality capture