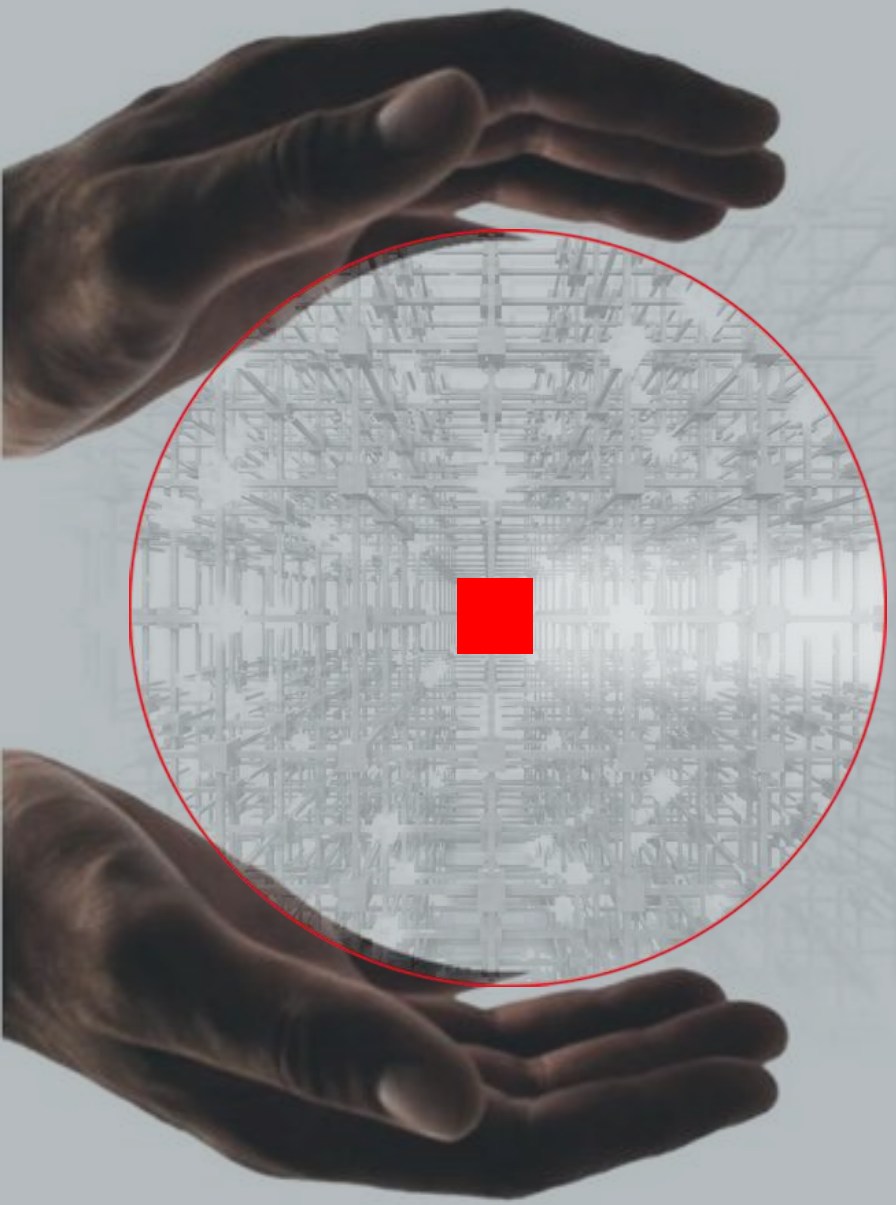

Applying Technologies Across the End-to-End PV Process to Increase Compliance and Quality

29 Oct 2015

Andrew Rut, Chief Executive Officer, MyMeds&Me

Michael Braun-Boghos, Director of Safety Analytics, Oracle Health Sciences

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Agenda

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  - In aggregate reporting, separate the logic layer from the presentation layer
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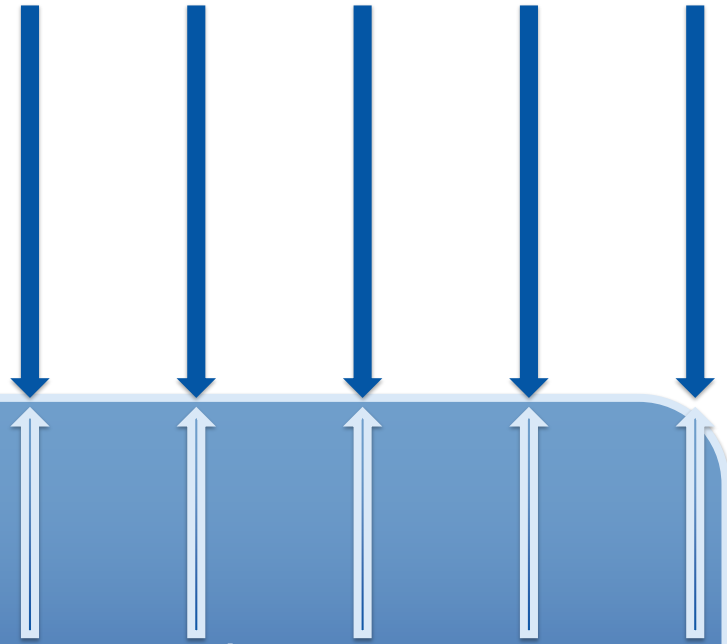
What does the evolving PV landscape look like? What are the challenges we face?

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

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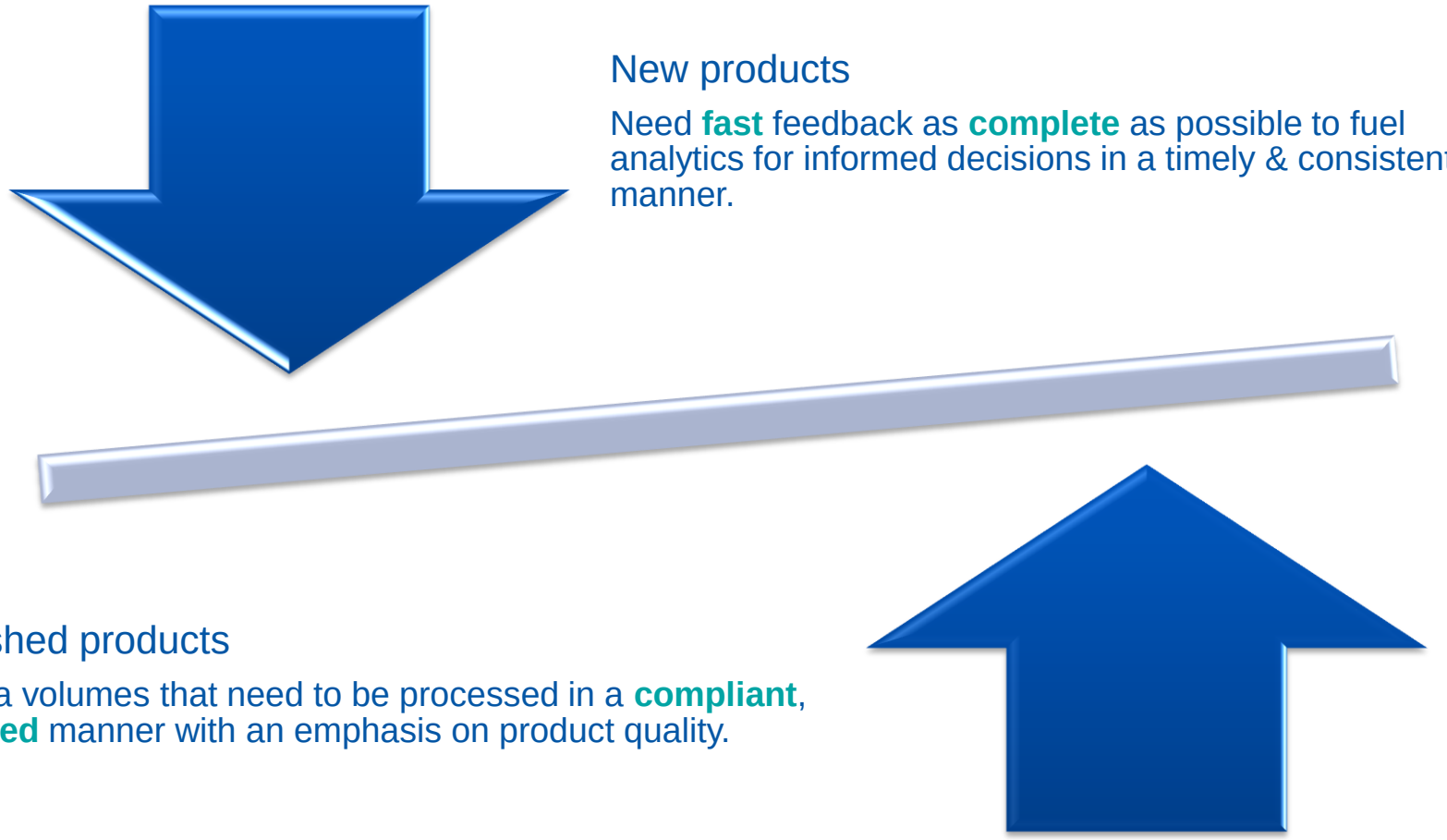
Quality: What form does it take and how does it change across product portfolios?



New products

Need **fast** feedback as **complete** as possible to fuel analytics for informed decisions in a timely & consistent manner.

Established products

High data volumes that need to be processed in a **compliant**, **automated** manner with an emphasis on product quality.

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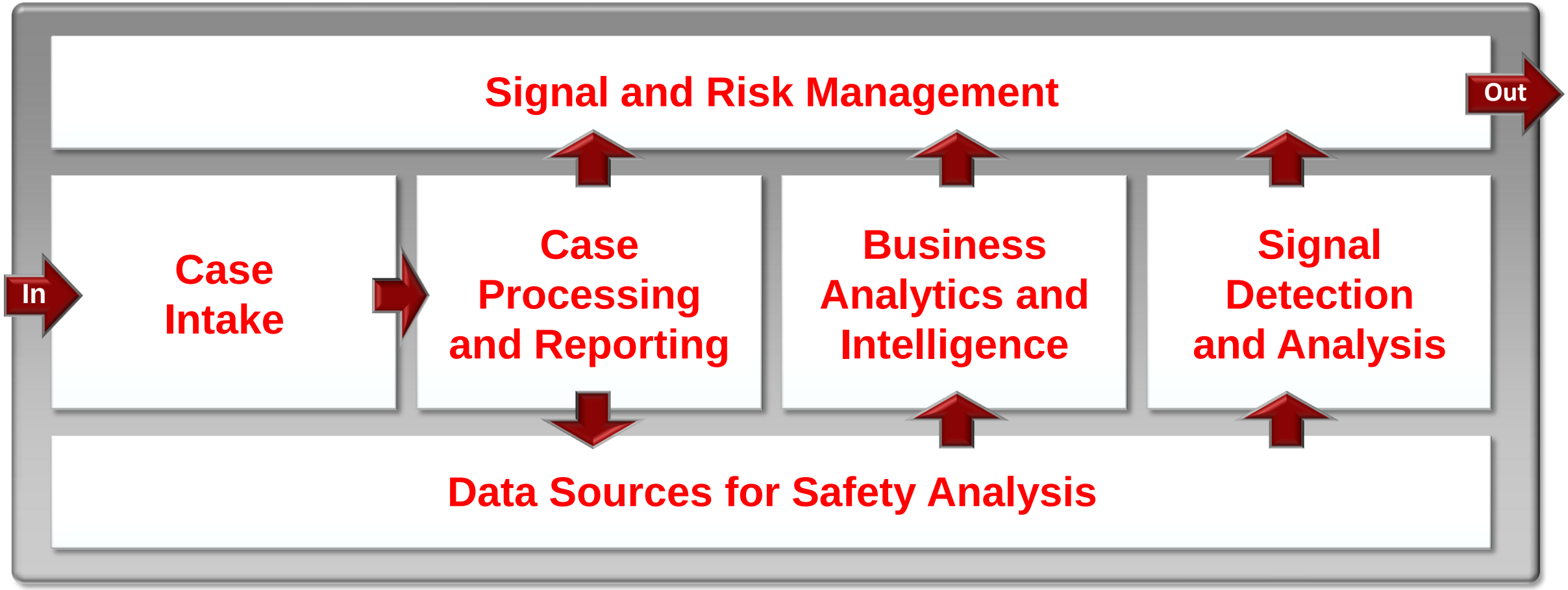
Product Safety and Pharmacovigilance

High-Level Business Processes Supported by Disparate Data



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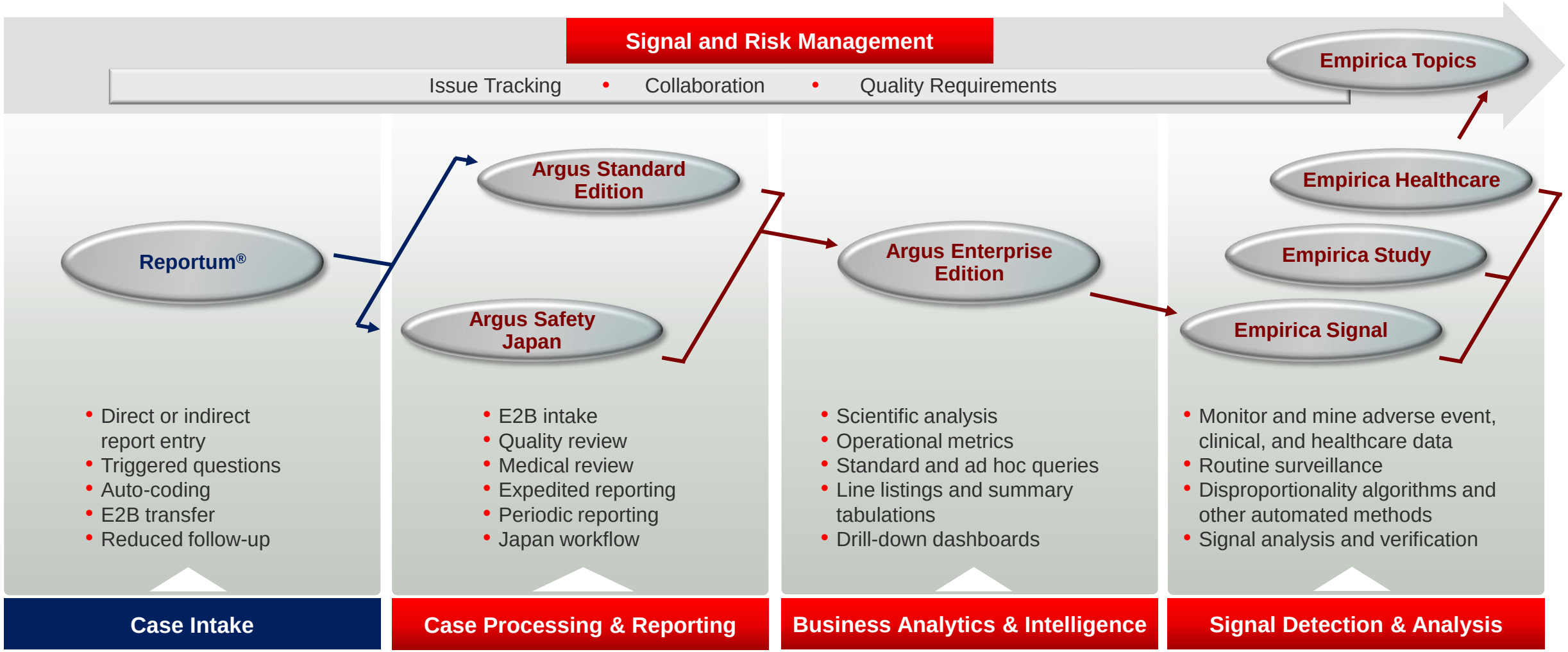
Oracle Health Sciences Safety Suite + MyMeds&Me Reportum®

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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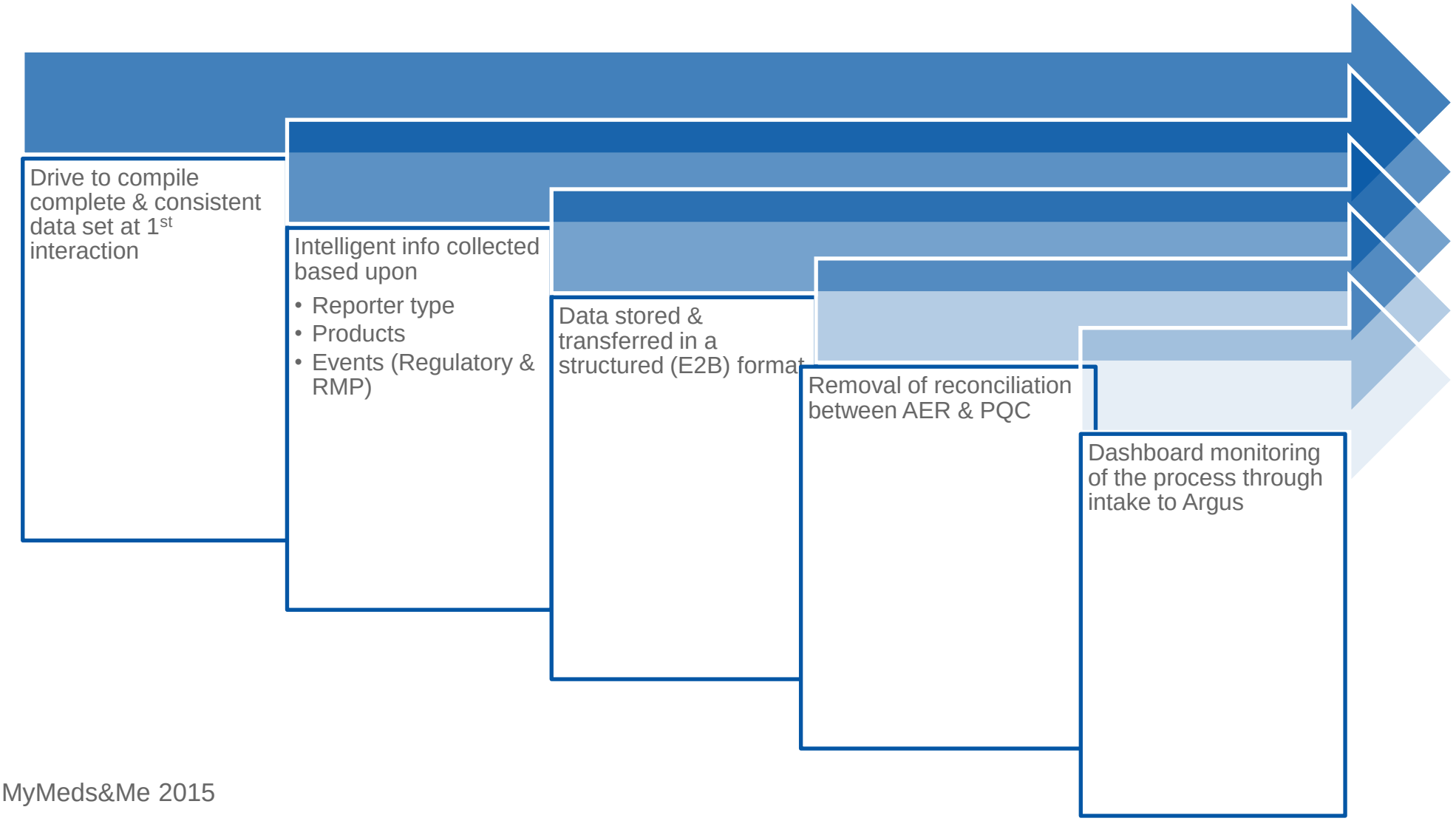
Quality across the portfolio – Into the detail…



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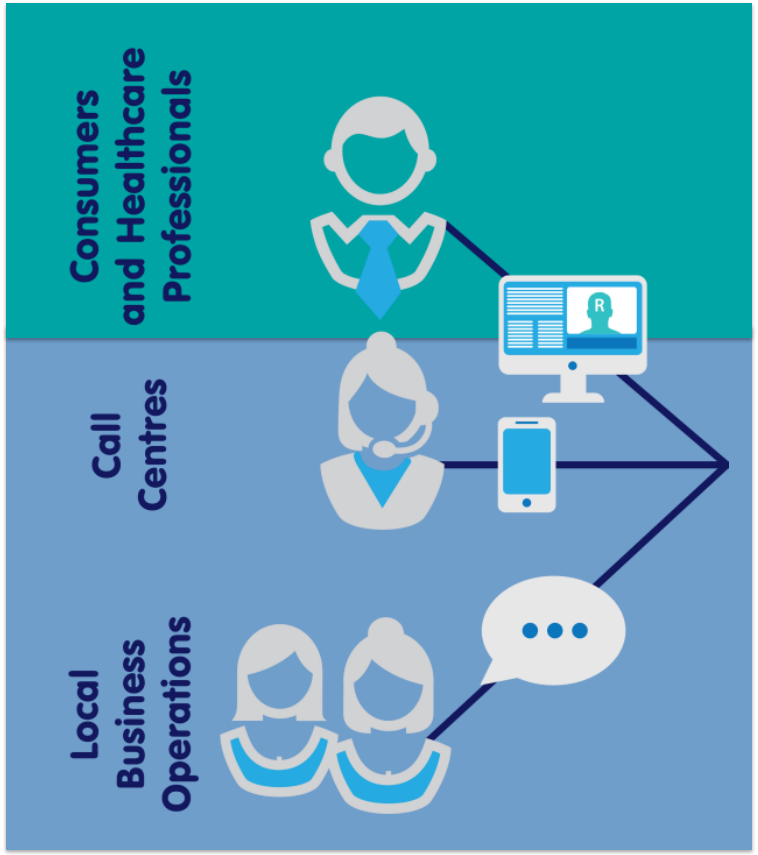
How does technology influence this?
End user experience & effectiveness

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

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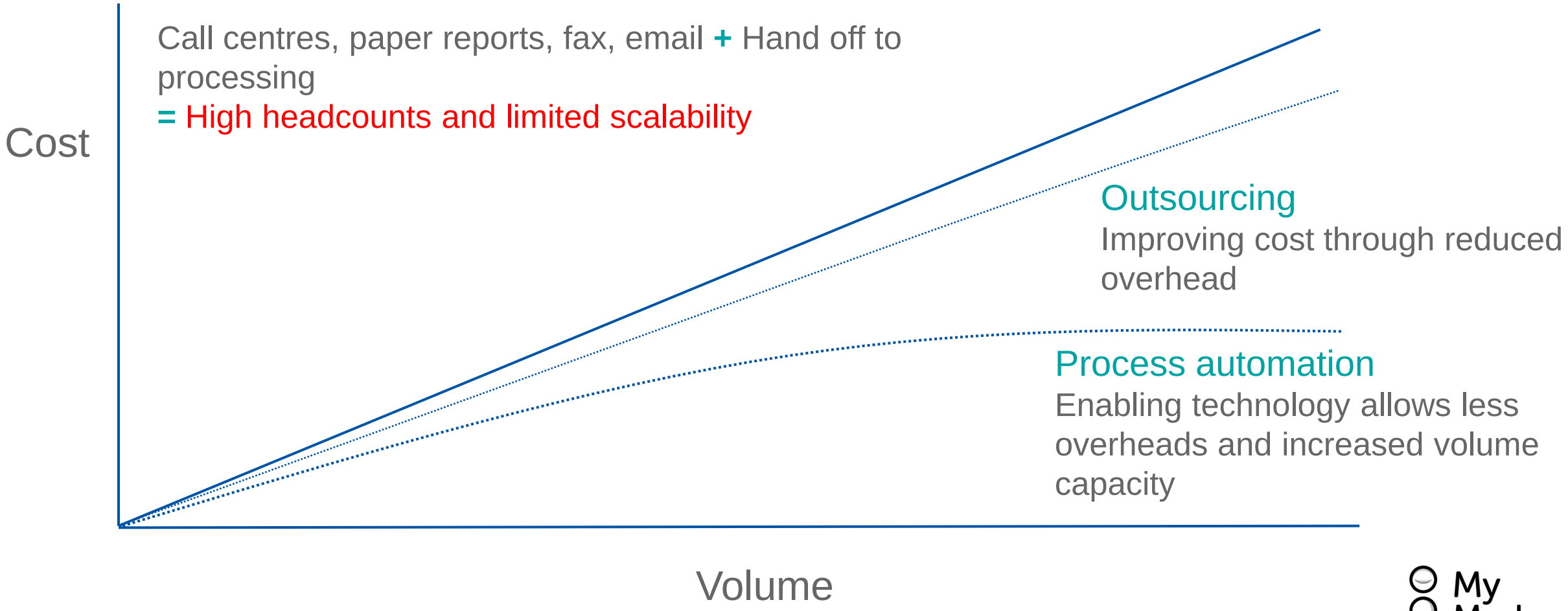
How does technology influence this?

Internal value & efficiency



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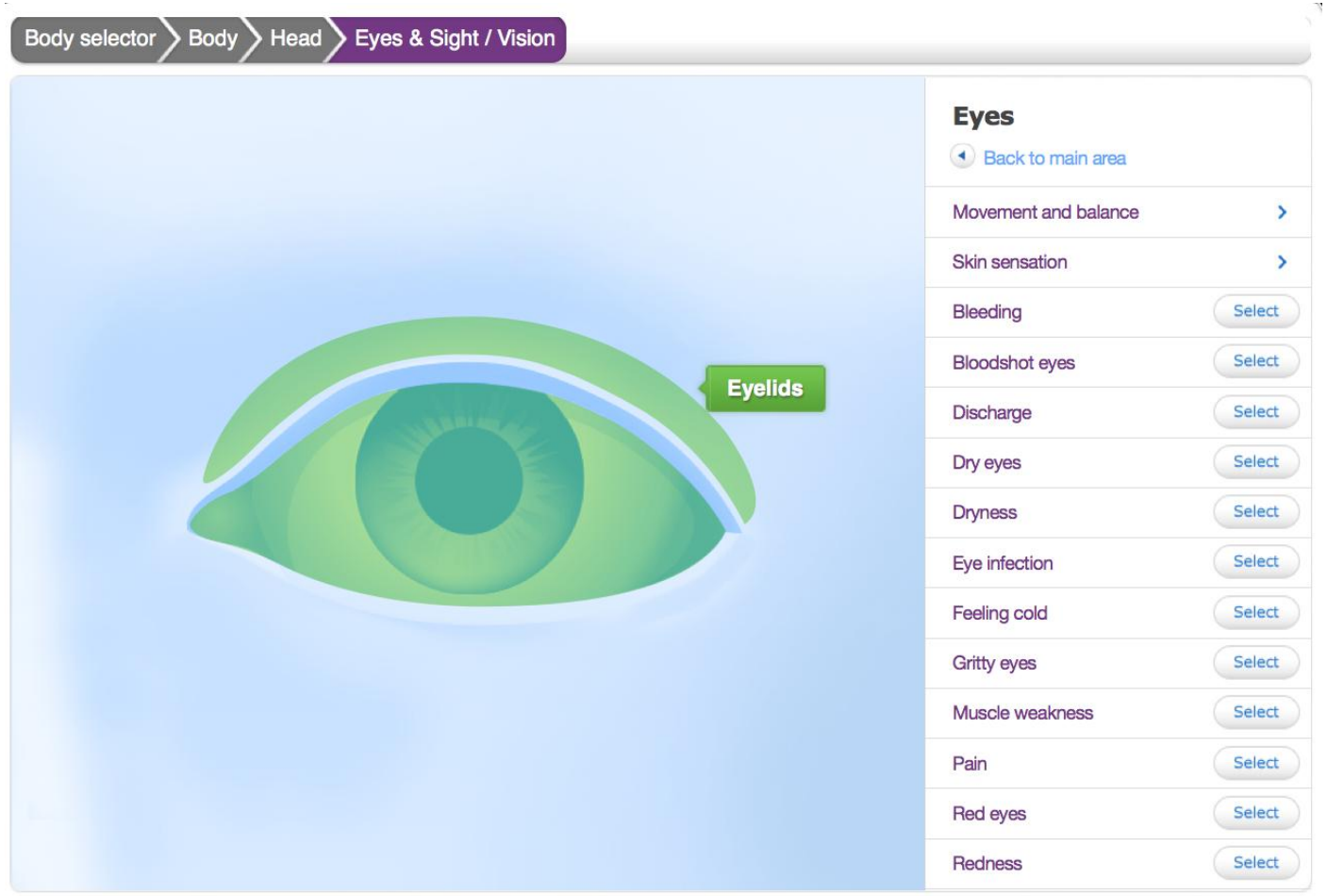
Intuitive, intelligent technology at its best



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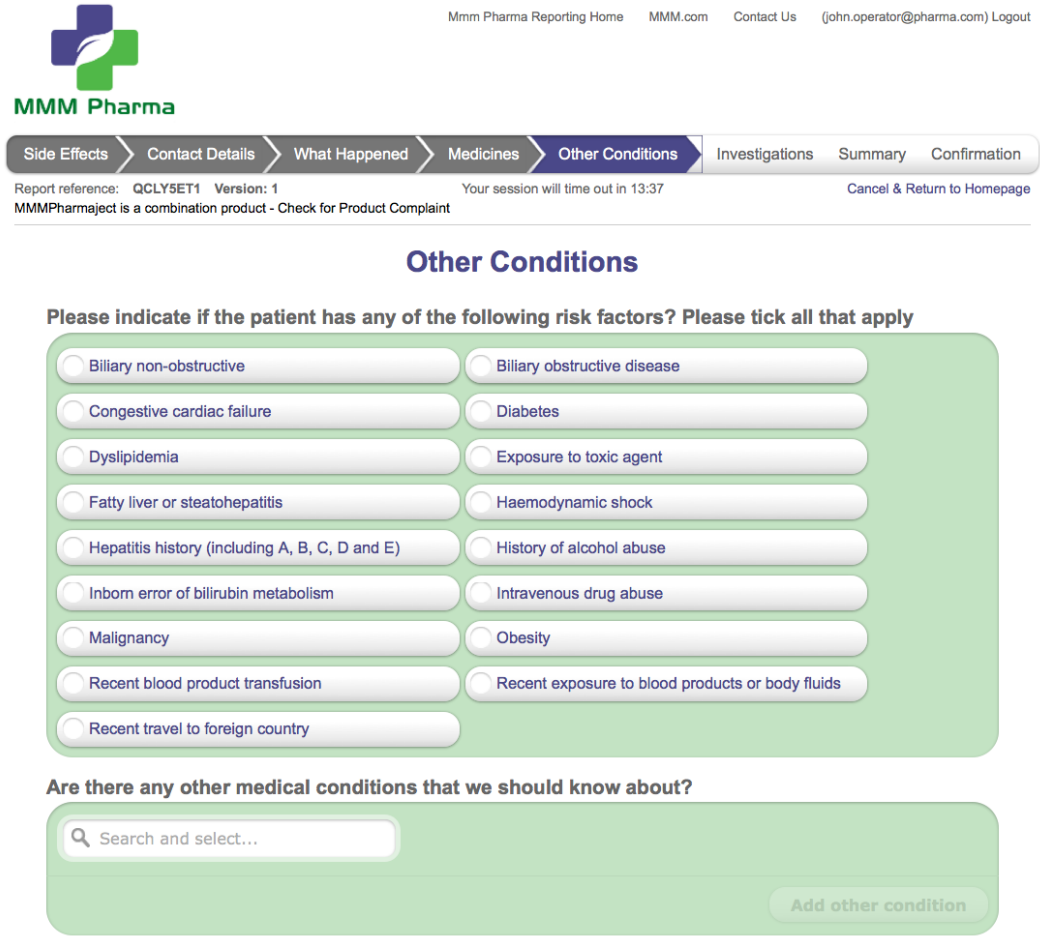

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Intuitive, intelligent technology at its best

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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.

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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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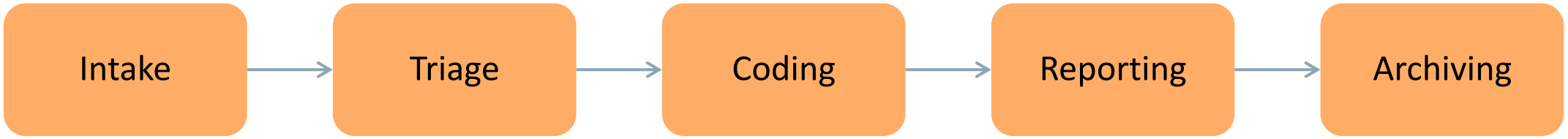
Automating Case Processing Steps

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



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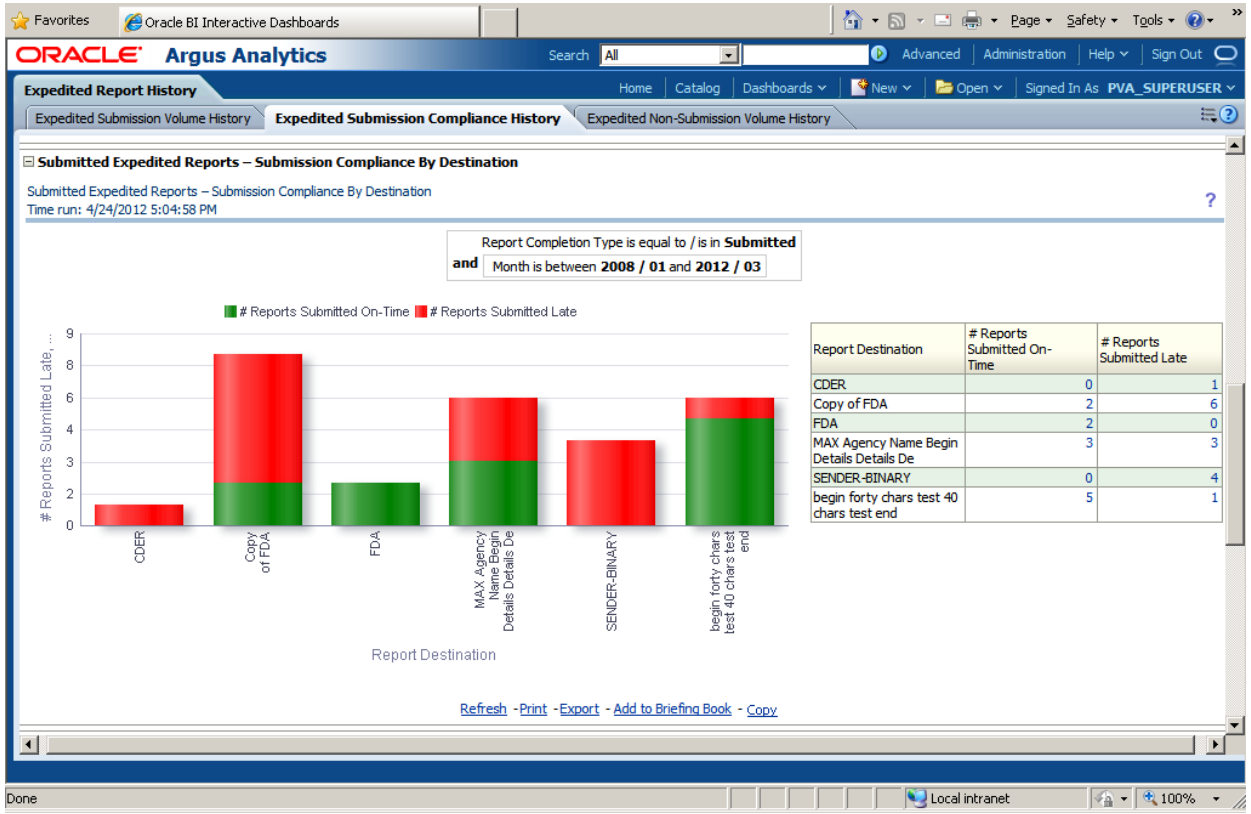
Tracking Operational Metrics

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



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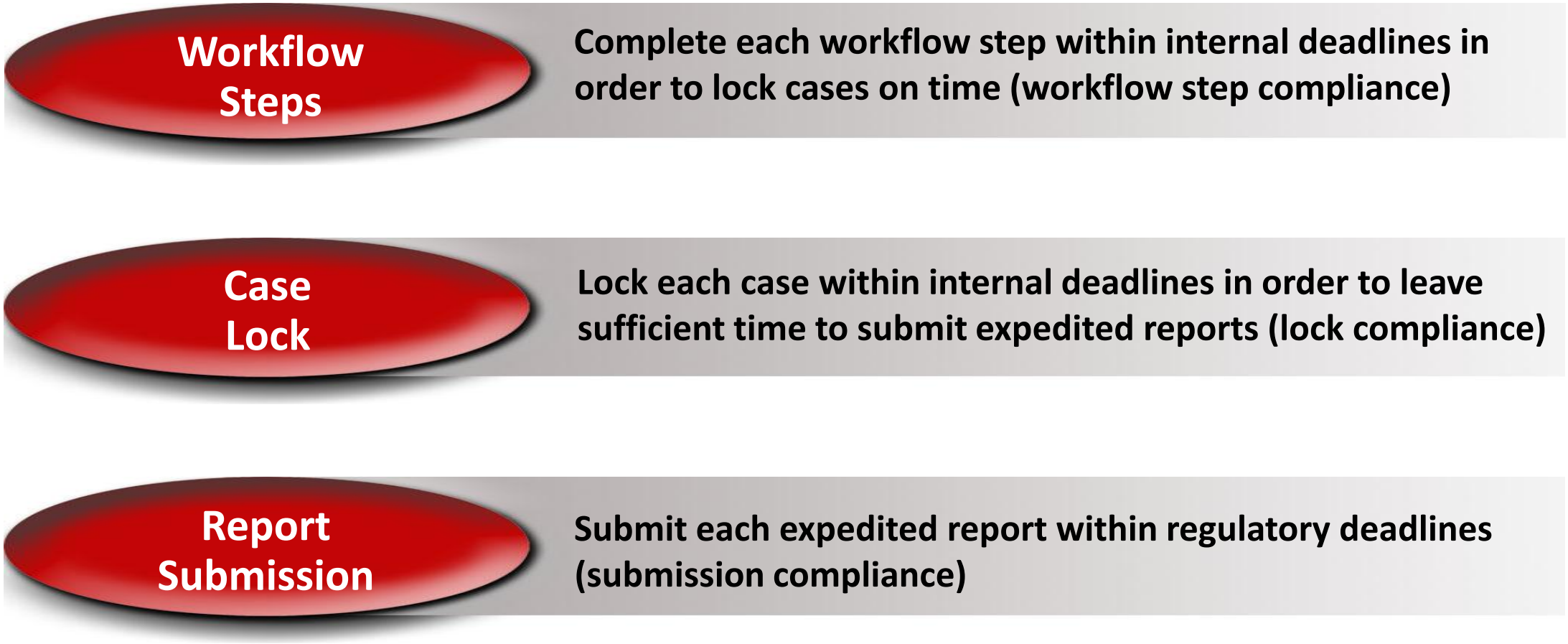
Compliance Throughout Case Processing



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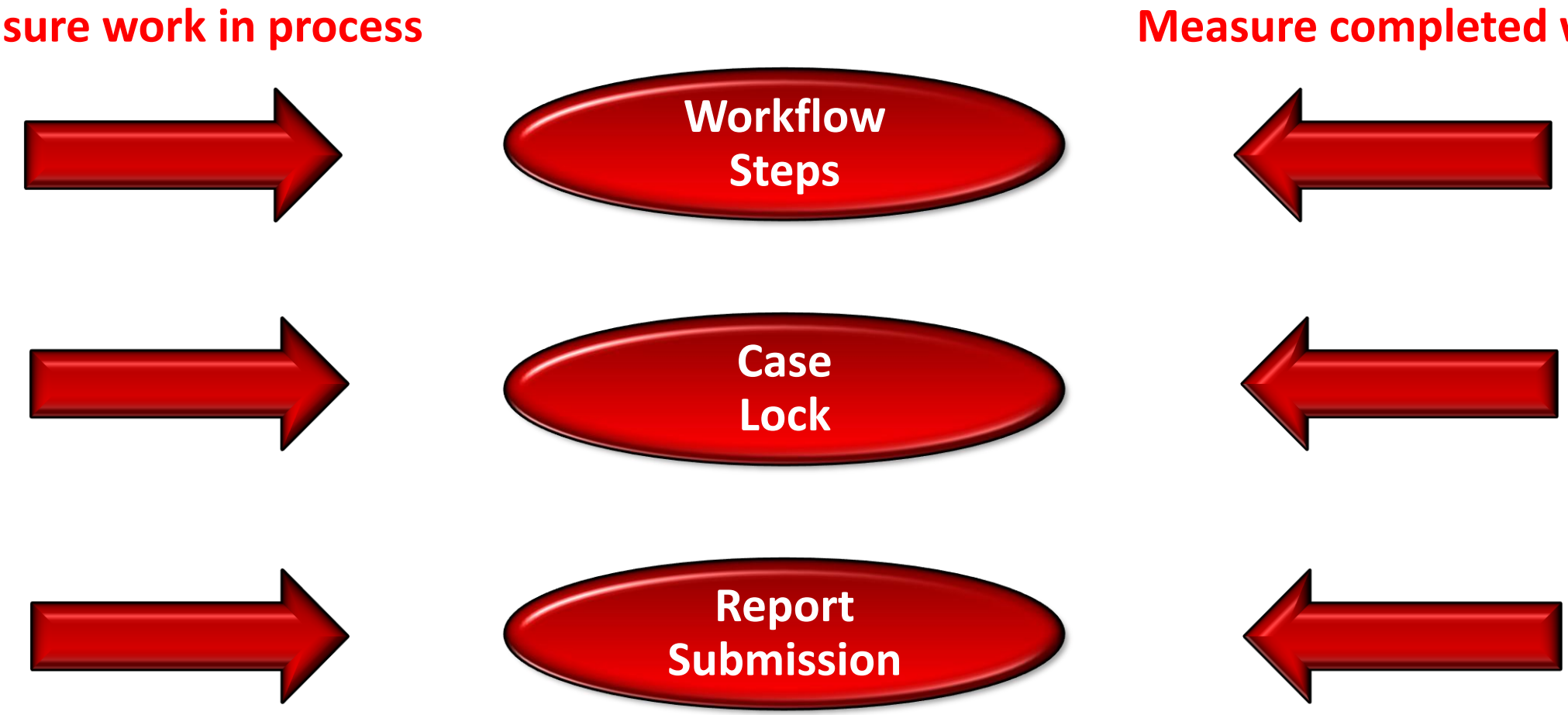
Current and Retrospective Metrics



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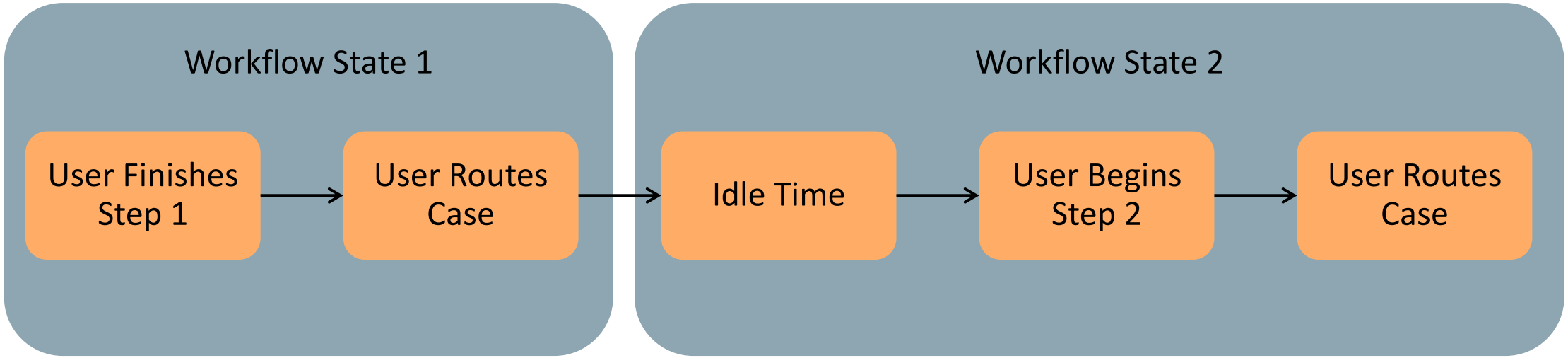
Idle Time Analysis

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



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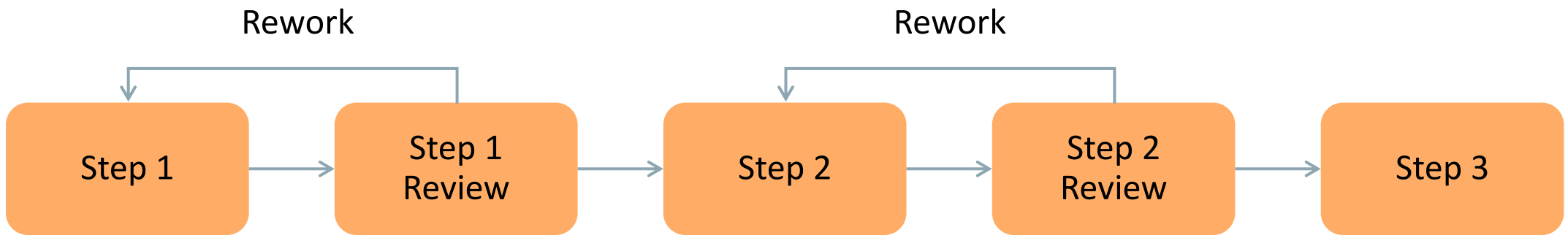
Case Rework Analysis

- 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

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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

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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

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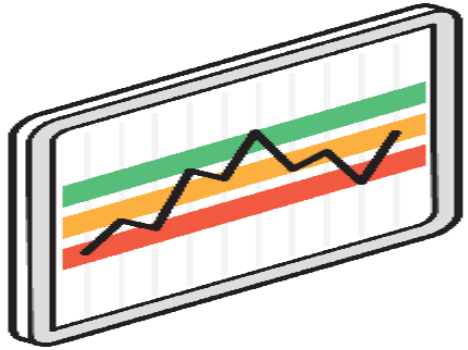
Report Performance

- 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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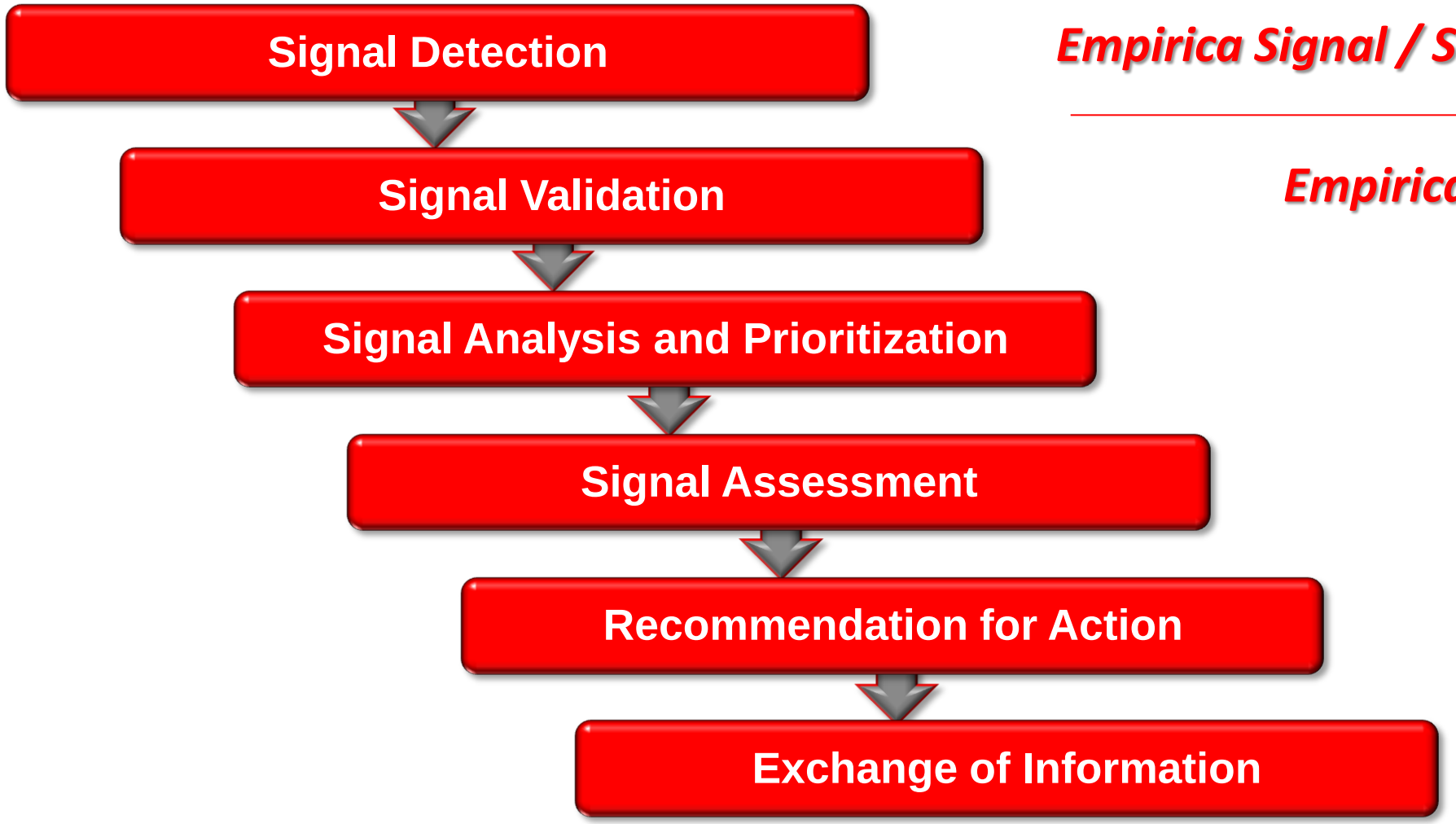
The Signal Management Process



Empirica Signal / Study / Healthcare

Empirica Topics

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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: I Reviewer: -- Drug: Ibuprofen SOC: --

Select View | Filter By Comments | Save As View | Manage Views

Columns and Rows | Print | Download | Select Rows

AERS Signal Configuration Rows are filtered

19 rows Sorted by Pediatric Alert, SOC, Pediatric EB05 2013Q1 desc

Rows Per Page: 200 Page 1 of 1

	Drug	SOC	Event	Pediatric Alert	Pediatric Nsince 2012Q4	Pediatric N 2013Q1	Pediatric EB05 2013Q1	Adult EB95 2013Q1	Comment	Topic Name	Topic 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			

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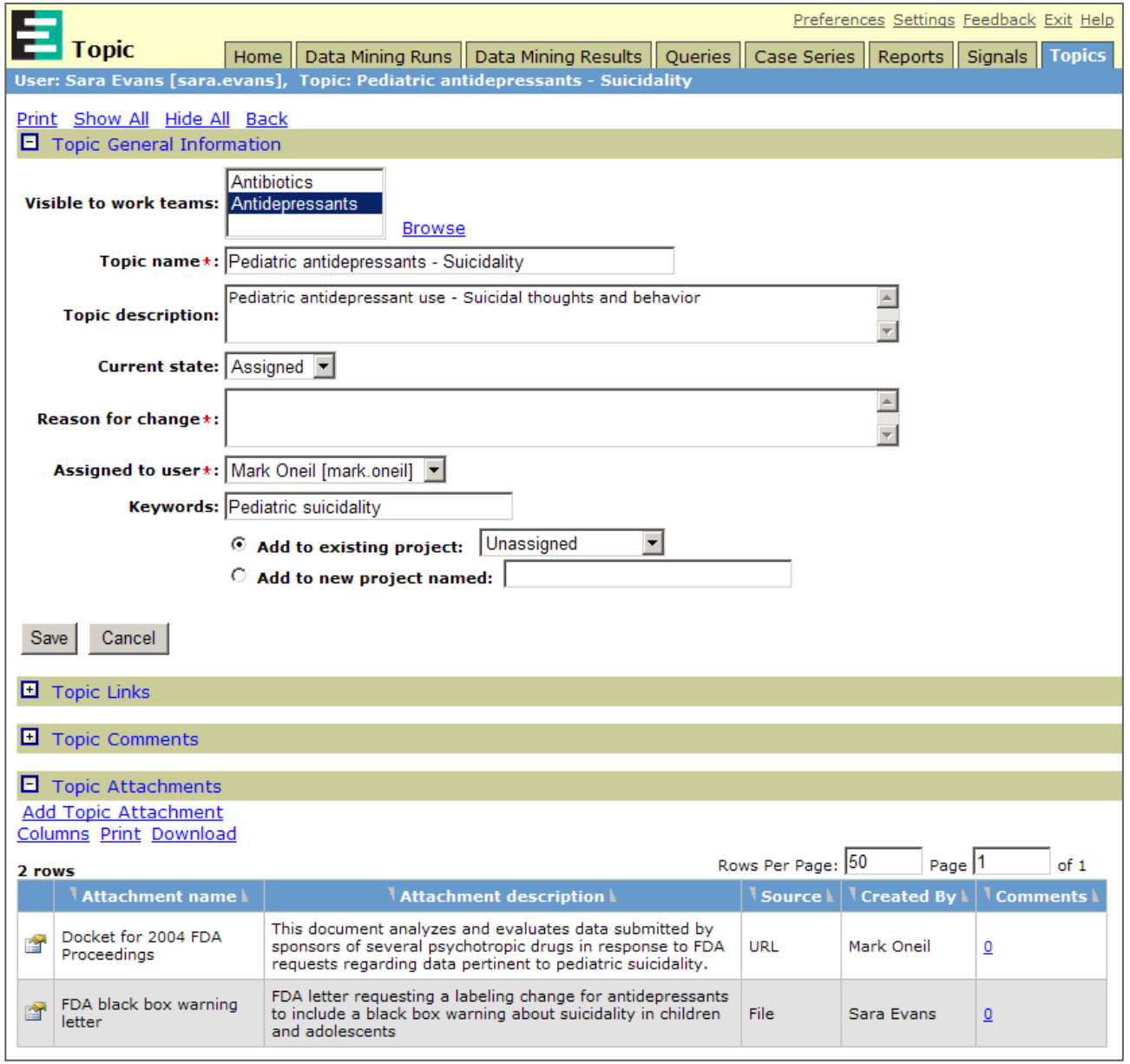
Building a Risk Knowledgebase



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Simplifying adverse event reporting and product quality capture