



Exploring the Application of Automation and Cognitive Technologies for Vaccine Pharmacovigilance

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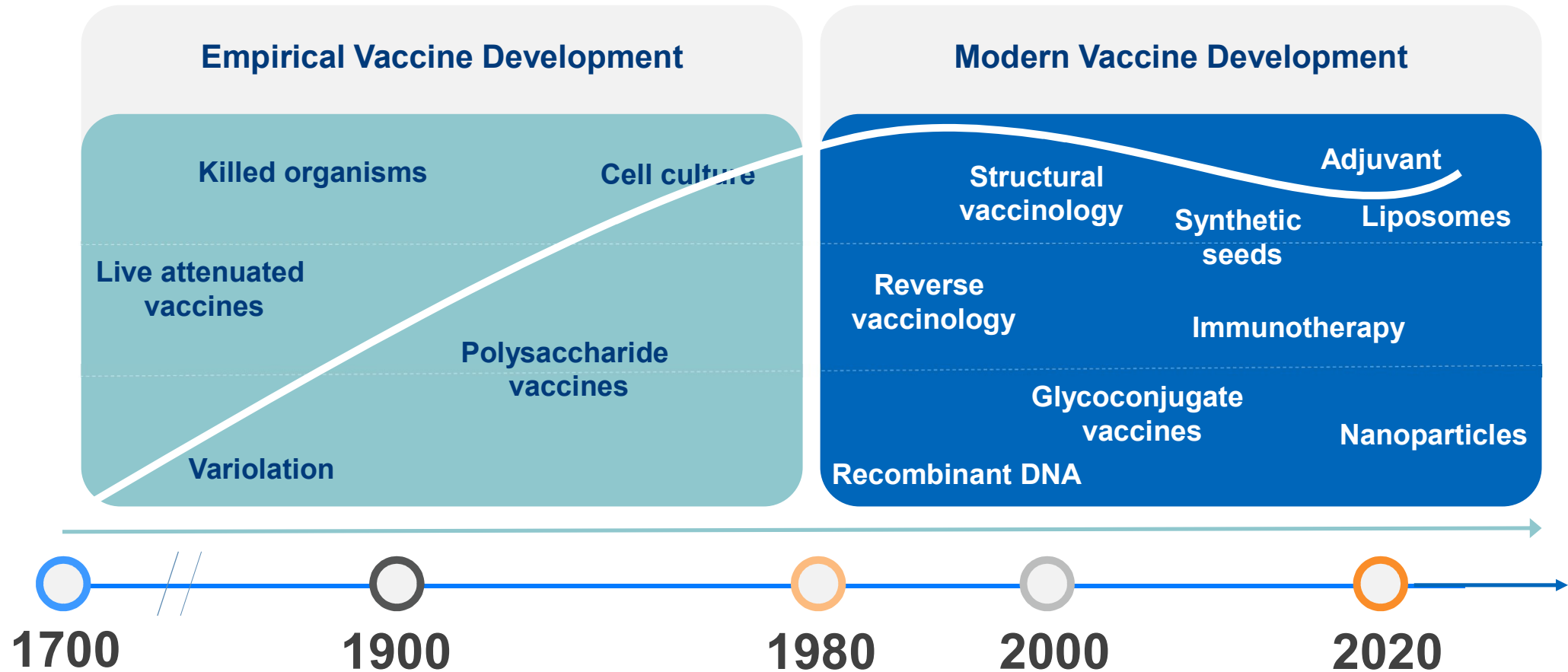


AGENDA

- 1. INNOVATIONS IN VACCINES**
- 2. CURRENT GAPS IN VACCINE SAFETY**
- 3. TECHNOLOGIES IN VACCINE SAFETY MANAGEMENT**
- 4. AUTOMATION IN VACCINE PHARMACOVIGILANCE**
- 5. EXPECTED BUSINESS OUTCOME OF AUTOMATION**

Innovations in Vaccines

Evolution of Vaccine Technologies



Current Gaps in Vaccine Safety

Vaccine Pharmacovigilance

Definition:

The science and activities relating to the *detection, assessment, understanding and communication* of AEFI and other vaccine- or immunization-related issues, and to the *prevention* of untoward effects of the vaccine or immunization.

Vaccine Safety?

Canadian Journal of Infectious Diseases and Medical Microbiology

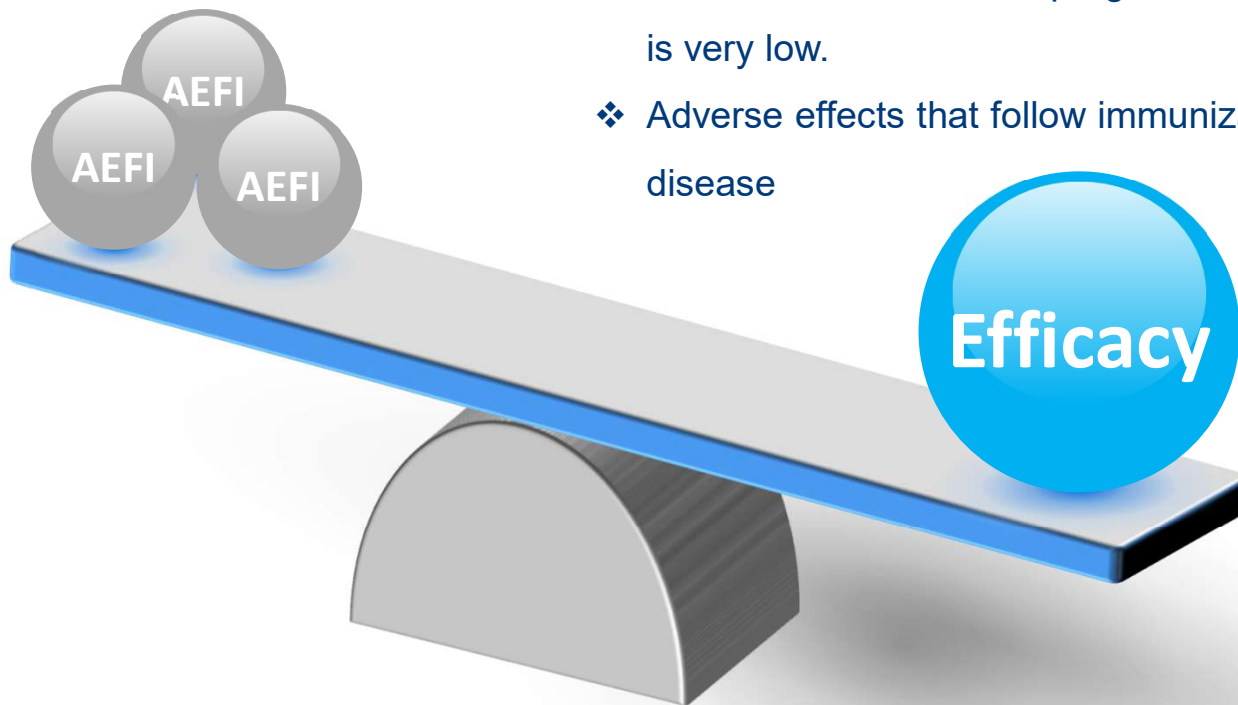
Rotavirus Vaccine Withdrawal in the United States: The Role of Postmarketing Surveillance

Science

Why a pandemic flu shot caused narcolepsy

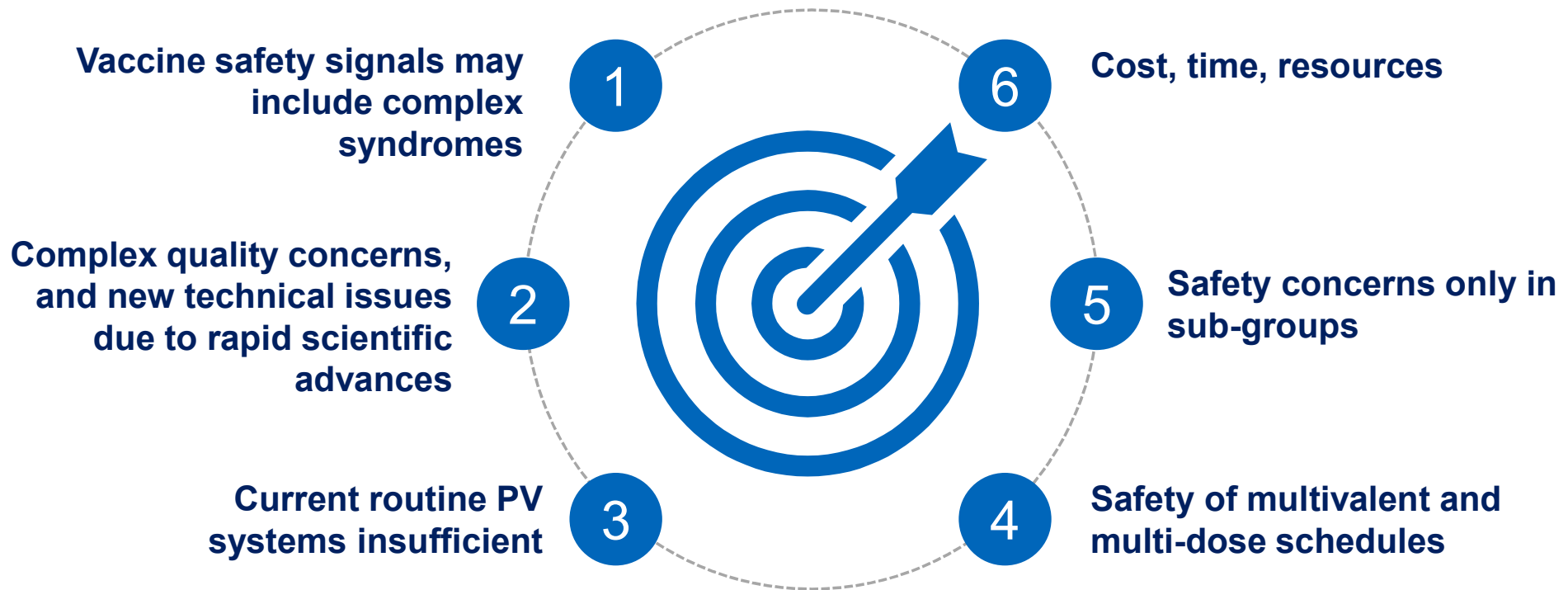
Vaccine Safety as Important as Efficacy

- ❖ Vaccines are required to have a higher-level of safety and lower levels of risk as compared with therapeutic medicinal products
- ❖ Most of the vaccination programs are aimed at children or infants, whose tolerance of risk is very low.
- ❖ Adverse effects that follow immunization are promptly noticeable as compared to the target disease



- ❖ Safety issues arising from vaccination require rapid action
- ❖ **Therefore the systems for handling the AEFI data should be robust, flexible, reliable and accurate**

Challenges with Vaccine Safety



Challenges with Vaccine Safety- Action Plan

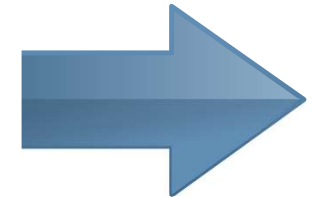
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STEP

Rapid Response

Any safety issues with vaccines should be dealt with rapidly; delays can result in loss of public confidence in vaccine



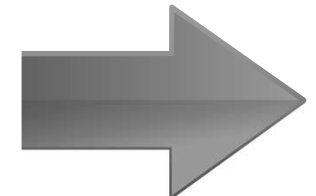
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STEP

Replacing Manual Methods

Manual methods for collection and assessment of individual cases may cause unnecessary delays and can be error prone



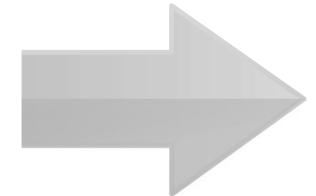
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STEP

Effective PV Systems

AEFI reporting system should be highly responsive, effective and should allow quality improvements



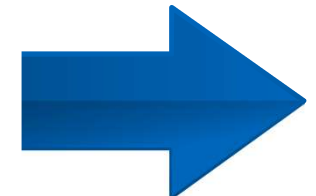
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STEP

Automation Technologies

Advanced automated systems should be incorporated for collection , processing, transmission of safety reports



Software Solutions for Vaccine Safety Management

Vaccine Pharmacovigilance Paradigm

Spontaneous Reports



Collection and processing of spontaneous reports of AEFI

STEP 1

Detecting any possible relation between an event and vaccine

STEP 2

Causality Hypothesis

Development of a causality hypothesis



STEP 3

Confirming or refuting the hypothesis

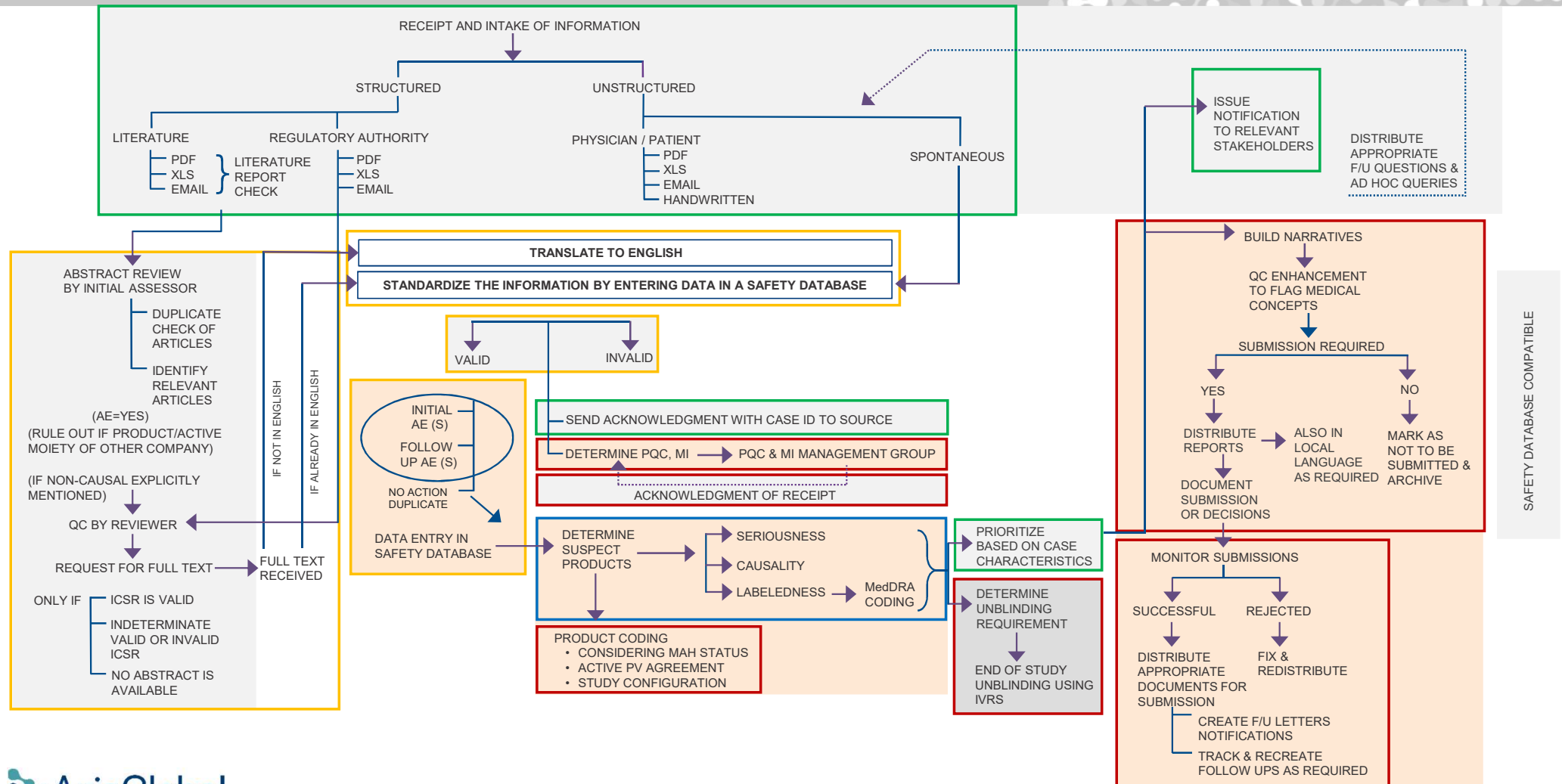


STEP 4

Testing Causality Hypothesis

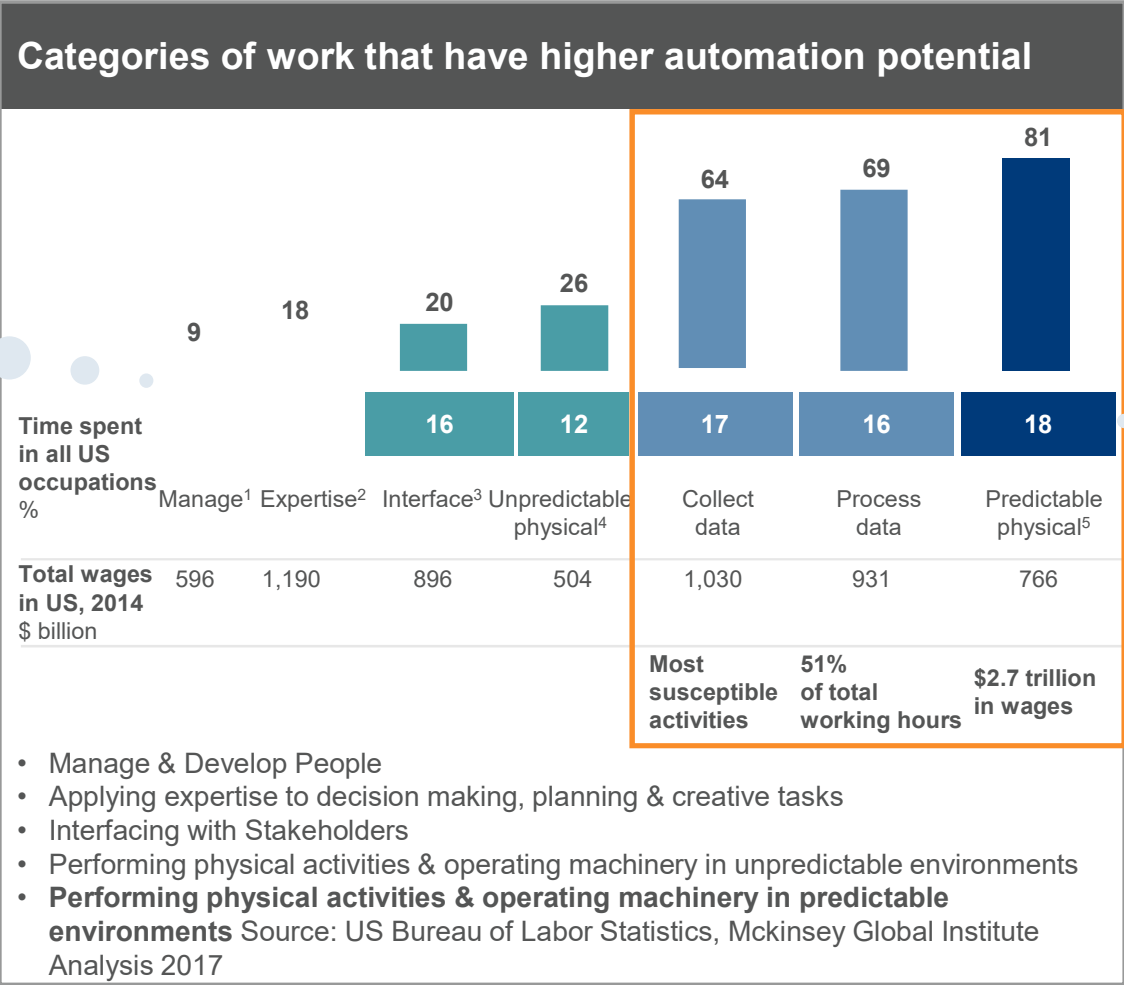
Signal Detection

Spontaneous Reports- Case Processing is Complex!



Where is Automation Likely to Impact the Most in Pharmacovigilance?

PSUR/PBRER
Writing,
Risk Management

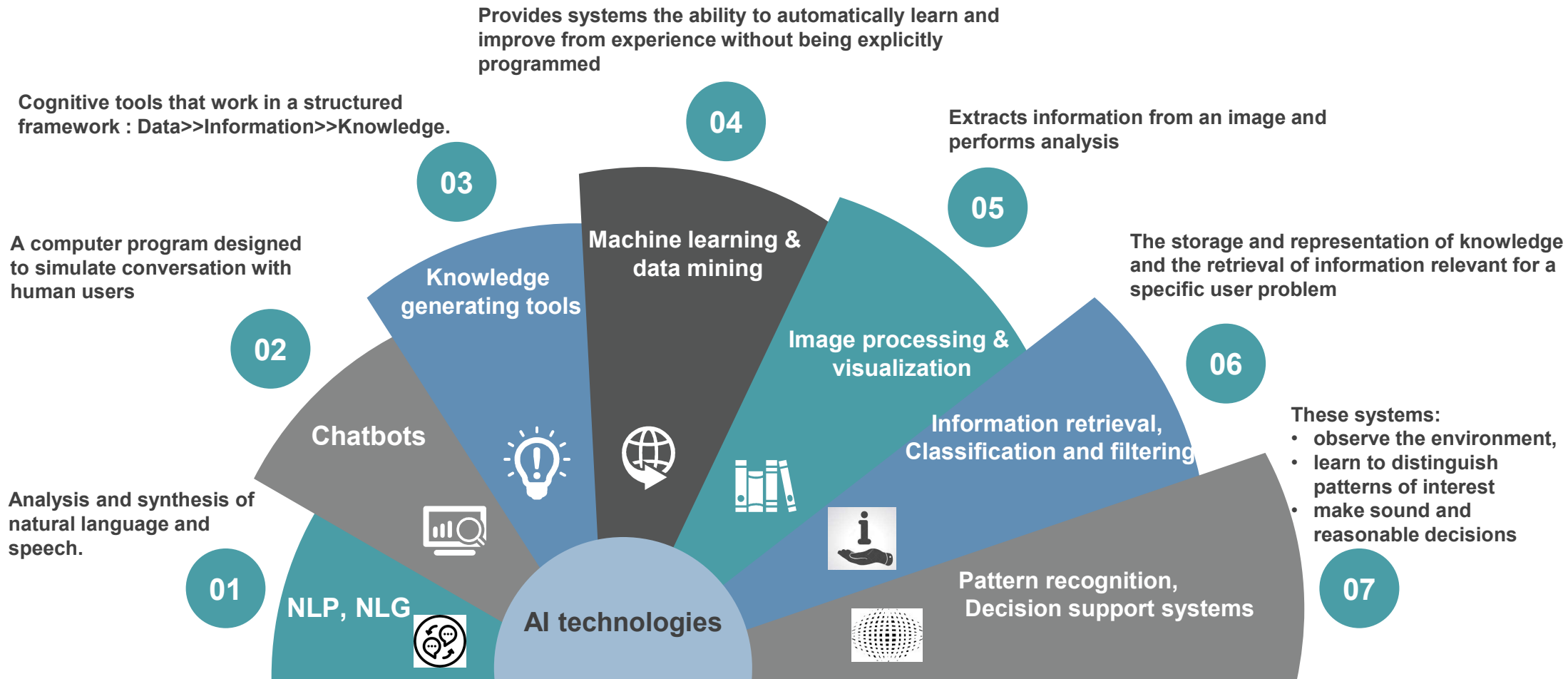


AE Case
Processing

Social
Upturn ?

Upending of
Jobs ?

Automation Technologies



About ArisGlobal



ArisGlobal is the leader in bringing to market IT-based solutions for the Life Science Industry, with a focus on the following industry specific domains:

-  Clinical Development
-  Regulatory Affairs
-  Safety/Pharmacovigilance
-  Medical Affairs



Why ArisGlobal

- 25+ years of Experience
- 200+ Current Clients
- 100+ customers on ArisGlobal Cloud
 - Largest PV solution on GxP complaint cloud
- 30 Customers on ISP-based, multi-tenant platform

Innovative

- First to market with Fully E2B R3 Compliant & xEVDMP/IDMP Ready solution
- First PV solution to have cognitive capabilities on the market
- Achieved 20% reduction in case processing time from day one
- First to introduce cloud to PV market

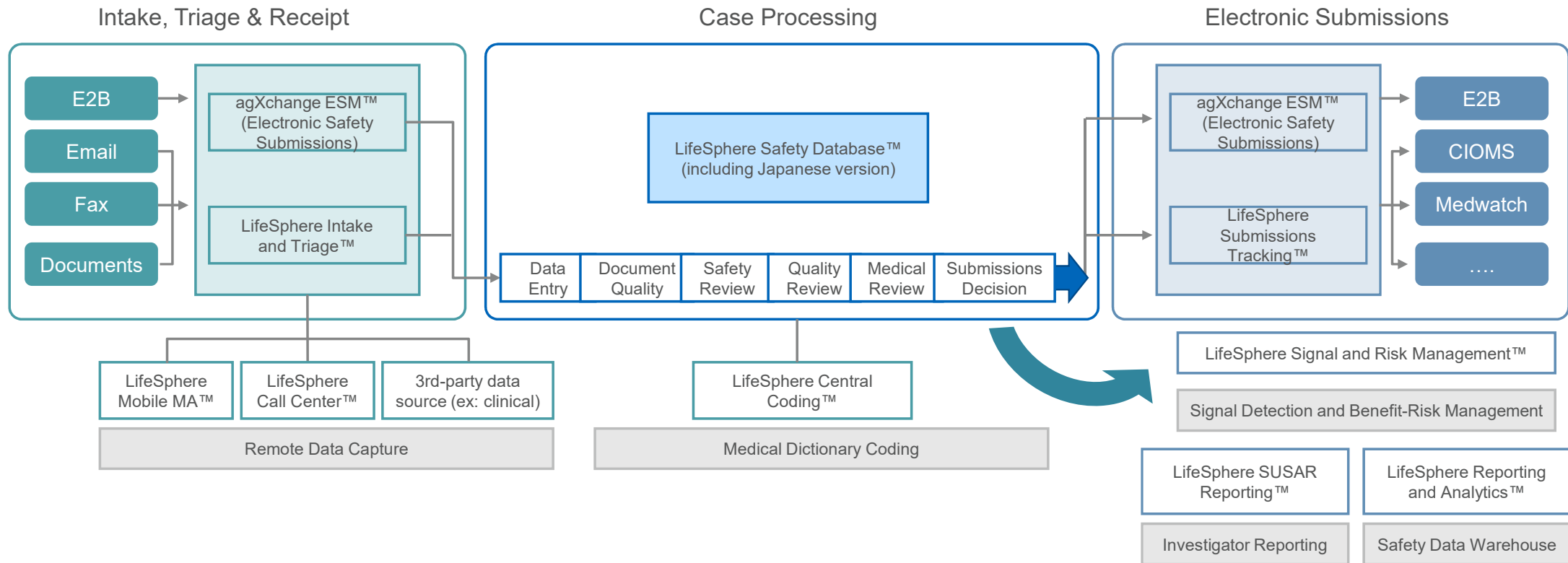
Proven

Trusted

- 8 Health Authorities using ArisGlobal Solutions
- 30 out of 50 large pharma
- Ongoing commitment by ArisGlobal to Life Sciences industry
- Proven track record in all areas of regulatory compliance including PV

LifeSphere Safety Multivigilance™

Integrated and streamlined end-to-end process for capturing, processing, reporting and benefit-risk analysis of adverse event cases.



ArisGlobal's Automation Approach



01

Consortium

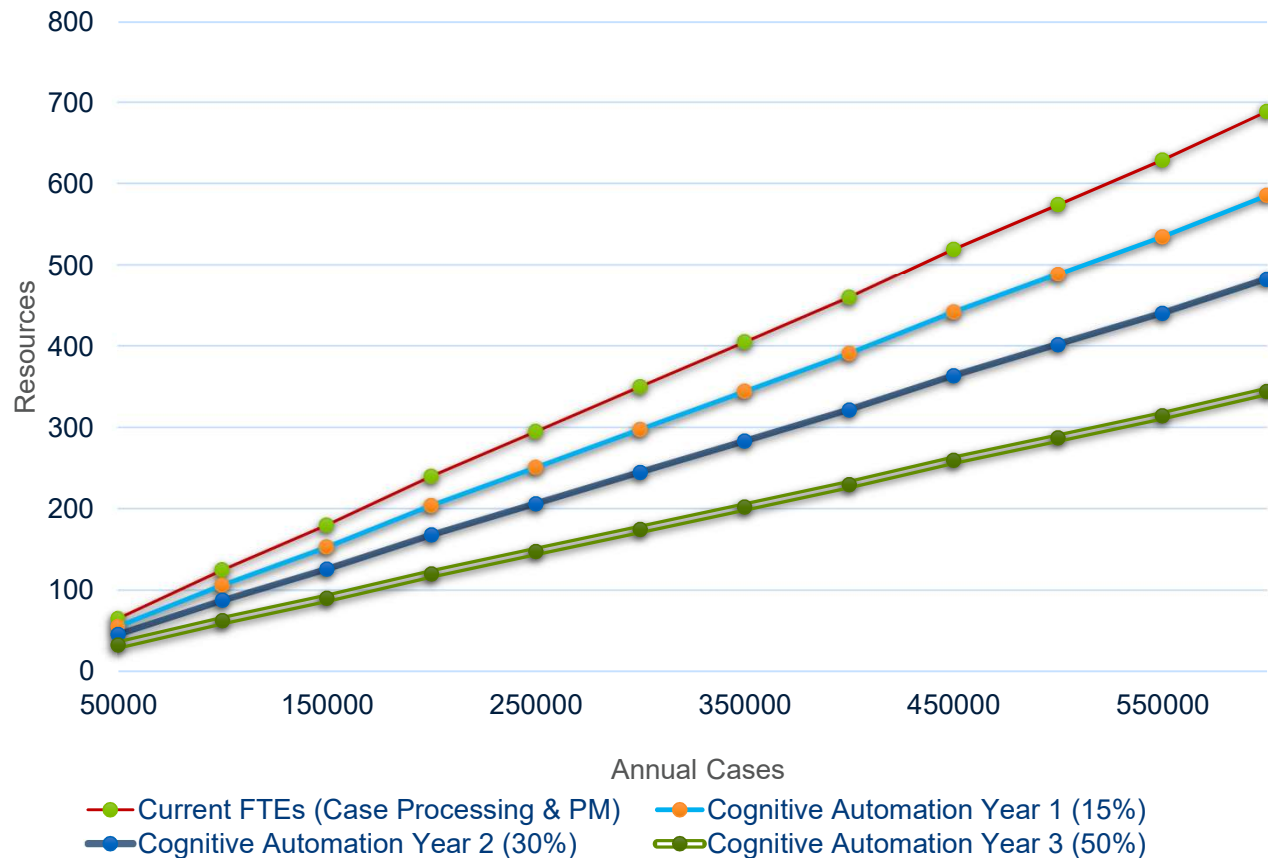
We have built a consortium with our 5 largest customers, together to achieve touchless non-serious processing of cases this year.

02

Regulators

Regulatory authorities are reviewing our technology/ algorithms for seriousness/triage as we work with 8 agencies across the world

Potential Impact of Automation on Case Processing



Current State



Year 1 (15%)



Year 2 (30%)



Year 3 (50%)

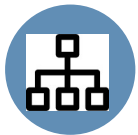


- 
- Increase in Cognitive Capability
 - Increase in Efficiency, Quality & Compliance
 - Decrease in FTEs & Cost

Automation in Vaccine Pharmacovigilance

Automation in Vaccine Pharmacovigilance

Areas in which automation is being applied in vaccine pharmacovigilance:



Case classification

To classify cases as AEFIs or not.



Medical Review

Review of case attributes.



Identification of new AEFIs

To identify previously unknown adverse events related to vaccination



Social media surveillance

To capture AEs not reported to spontaneous reporting systems



Medical literature monitoring

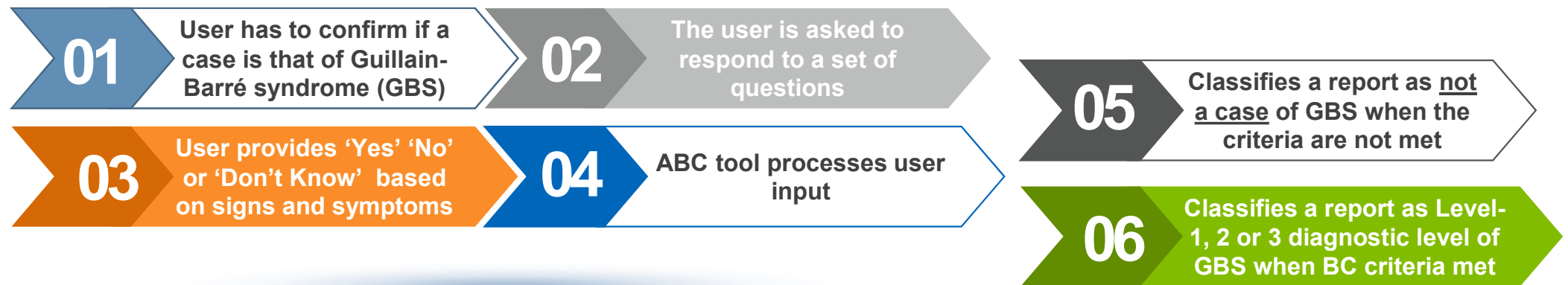
To monitor new cases reported in medical literature

Automation in AEFI Case Classification

Automation of case classification of reports can increase reliability of the safety signals detected.

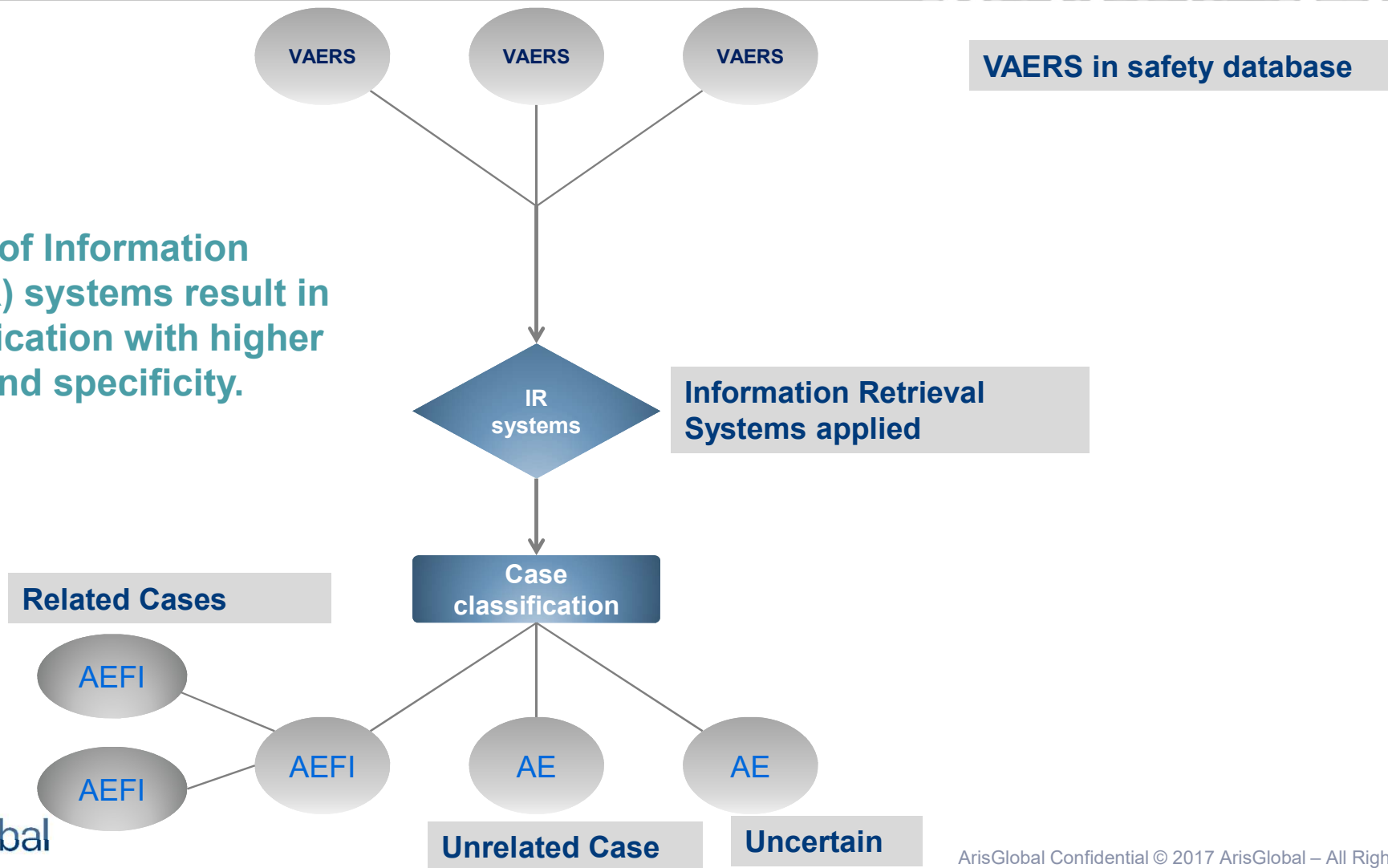
Automatic Brighton Classification (ABC) Tool:

- ✓ It is an online tool for case definition
- ✓ Has a rule-based algorithm
- ✓ Allows the confirmation of AEFIs based on user input on signs and symptoms of a case
- ✓ Assessment is based on Brighton Collaboration (BC) defined criteria for a specific AEFI



Automation in AEFI Case Classification

Application of Information Retrieval (IR) systems result in case classification with higher sensitivity and specificity.



Automation in Medical Review

The text mining tools can extract key clinical features from narratives to aid in the automated review of adverse event reports

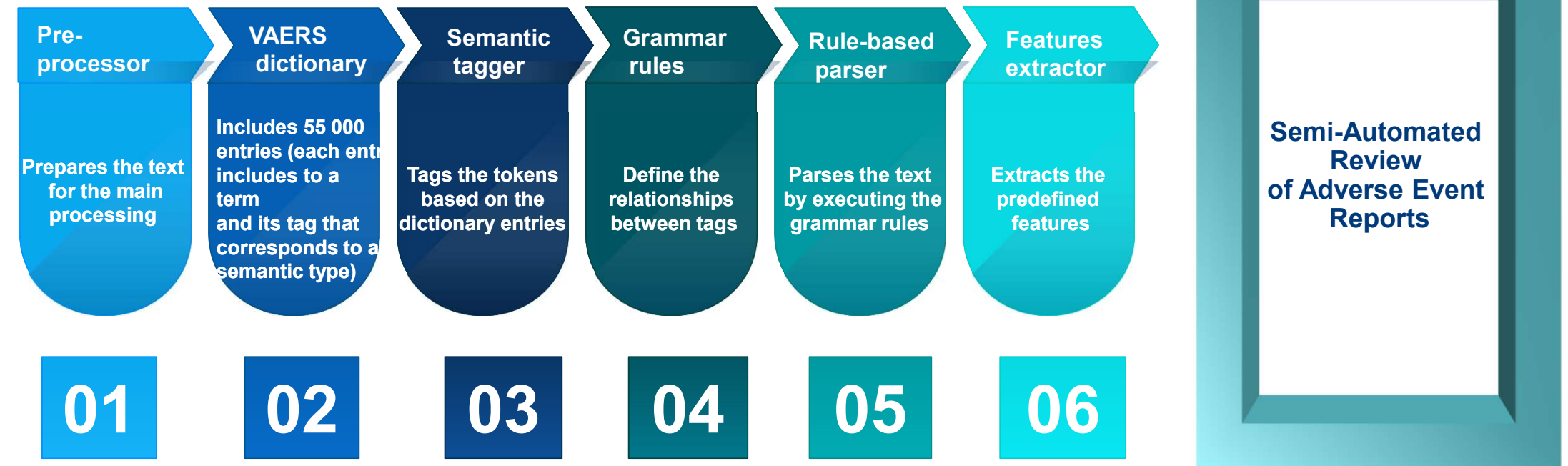
Key functions of an automated text mining system are:

- Can **recognize** essential text in the narrative
- Can **differentiate** a reported symptom and an actual diagnosis in the narrative
- Can **extract** key features of a case
- Can perform **organization** of key medical concepts in a narrative



Automation in Medical Review

The text mining system components and functions:



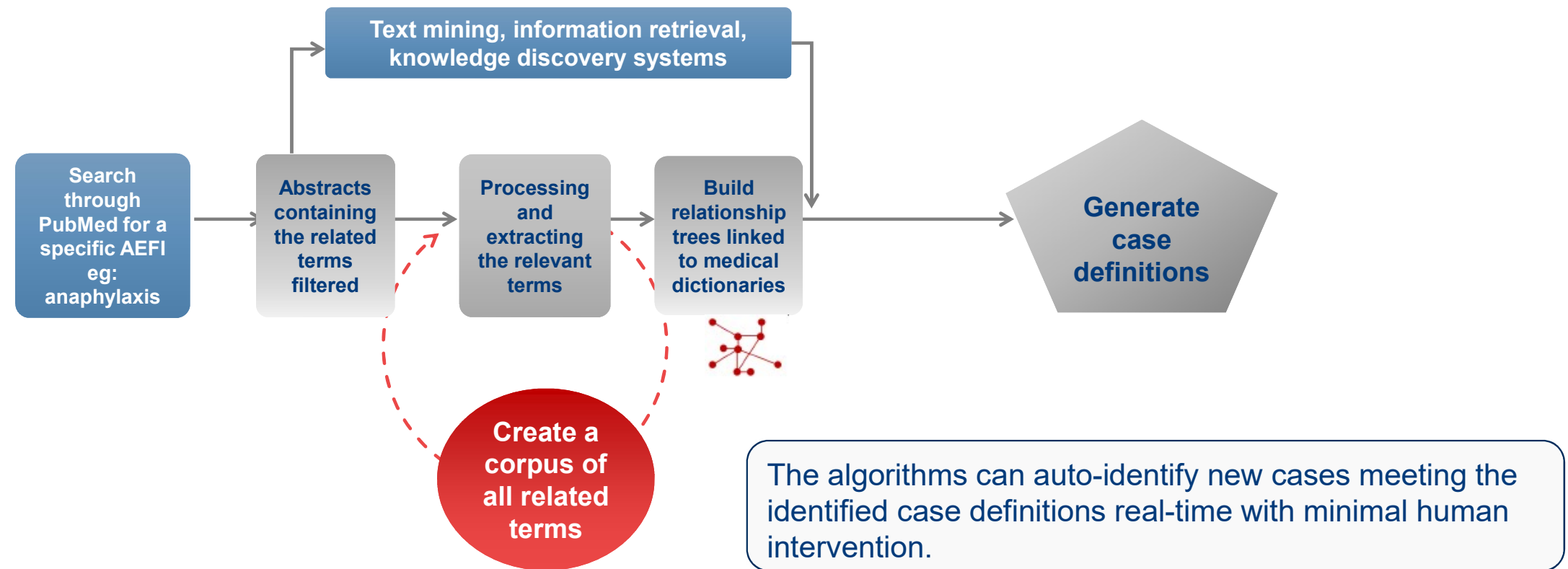
Automated Definition of New Adverse Events

Automation with literature-based reasoning:

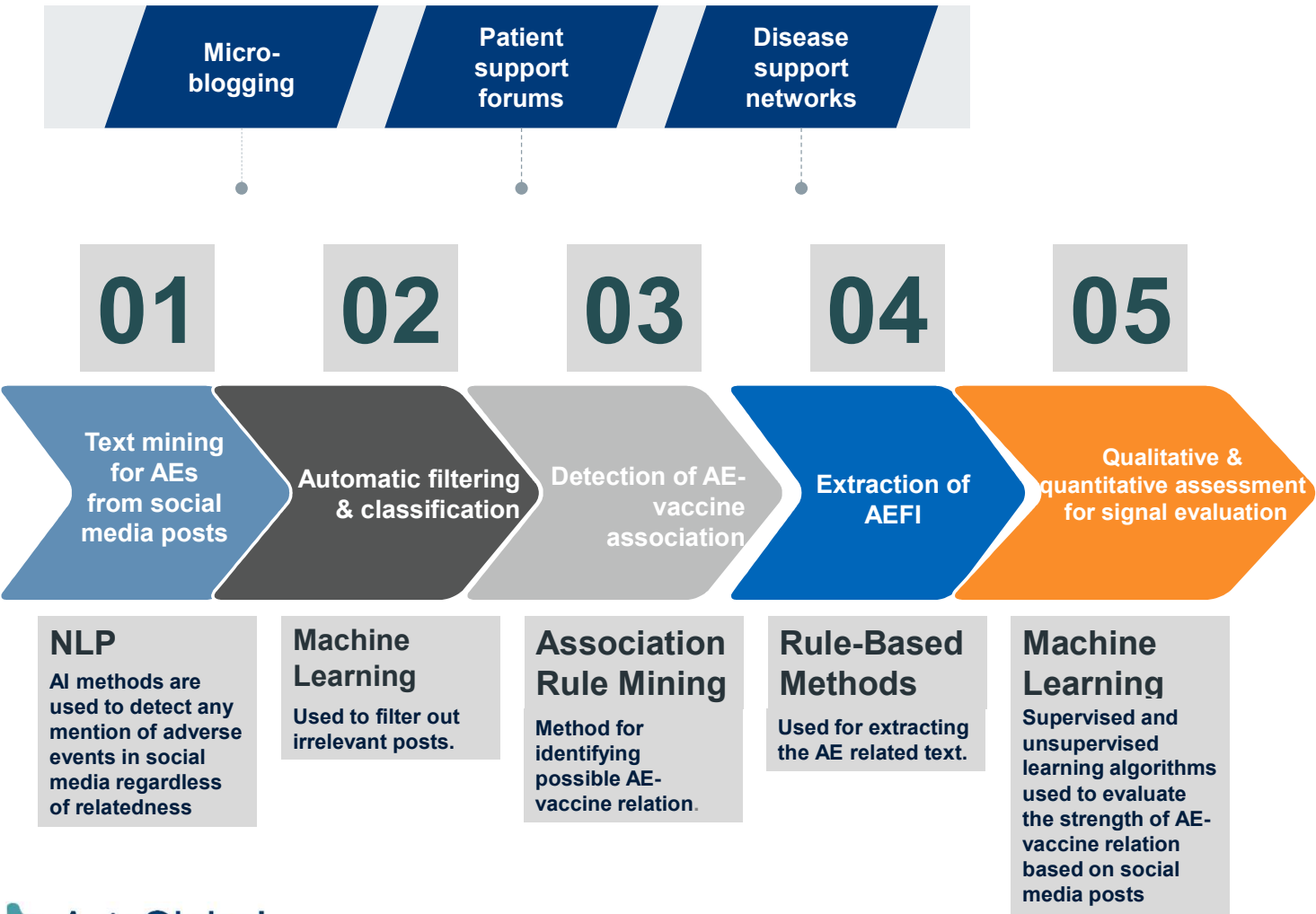
- The technology builds new case definitions based on cross-case patterns in literature.
- The case definitions are built using text mining, information retrieval systems and knowledge discovery systems from biomedical literature.
- The findings from biomedical literature are translated into algorithms.
- The algorithms automatically identify the cases of a specific condition.
- The algorithms can be updated continuously based on new findings.

Automated Definition of New Adverse Events

Workflow for literature-based new AEFI case definitions:

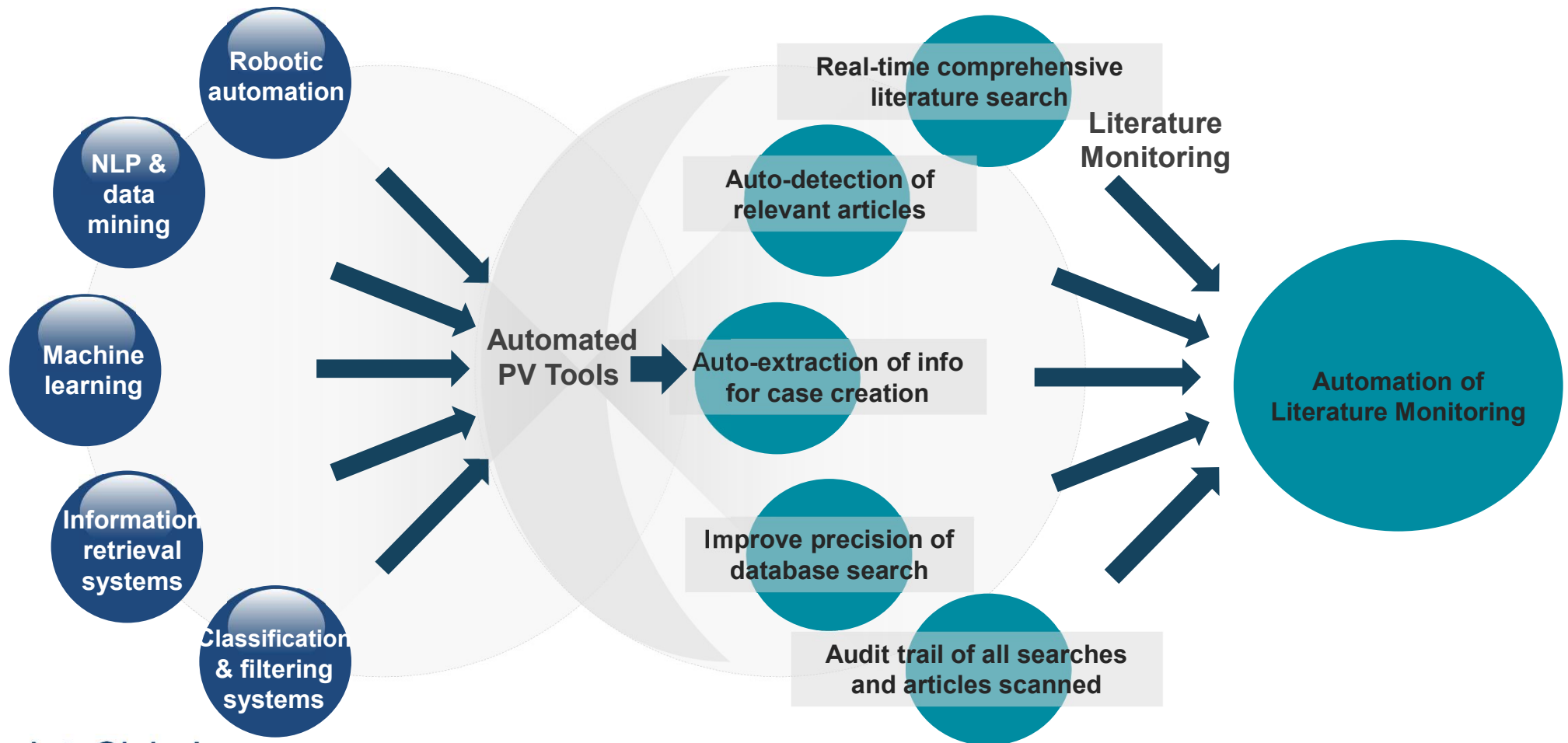


Social Media Surveillance of AEFI



- ❖ Advanced cognitive tools can be applied to auto-detect vaccine names and reaction terms from social media posts
- ❖ Machine learning algorithms can be applied for performing complex statistical analyses
- ❖ Hidden AE reporting patterns can be detected
- ❖ PV data from various sources can be combined
- ❖ Results in potentially neutralizing biases from different sources such as spontaneous reports, literature, social media, PASS

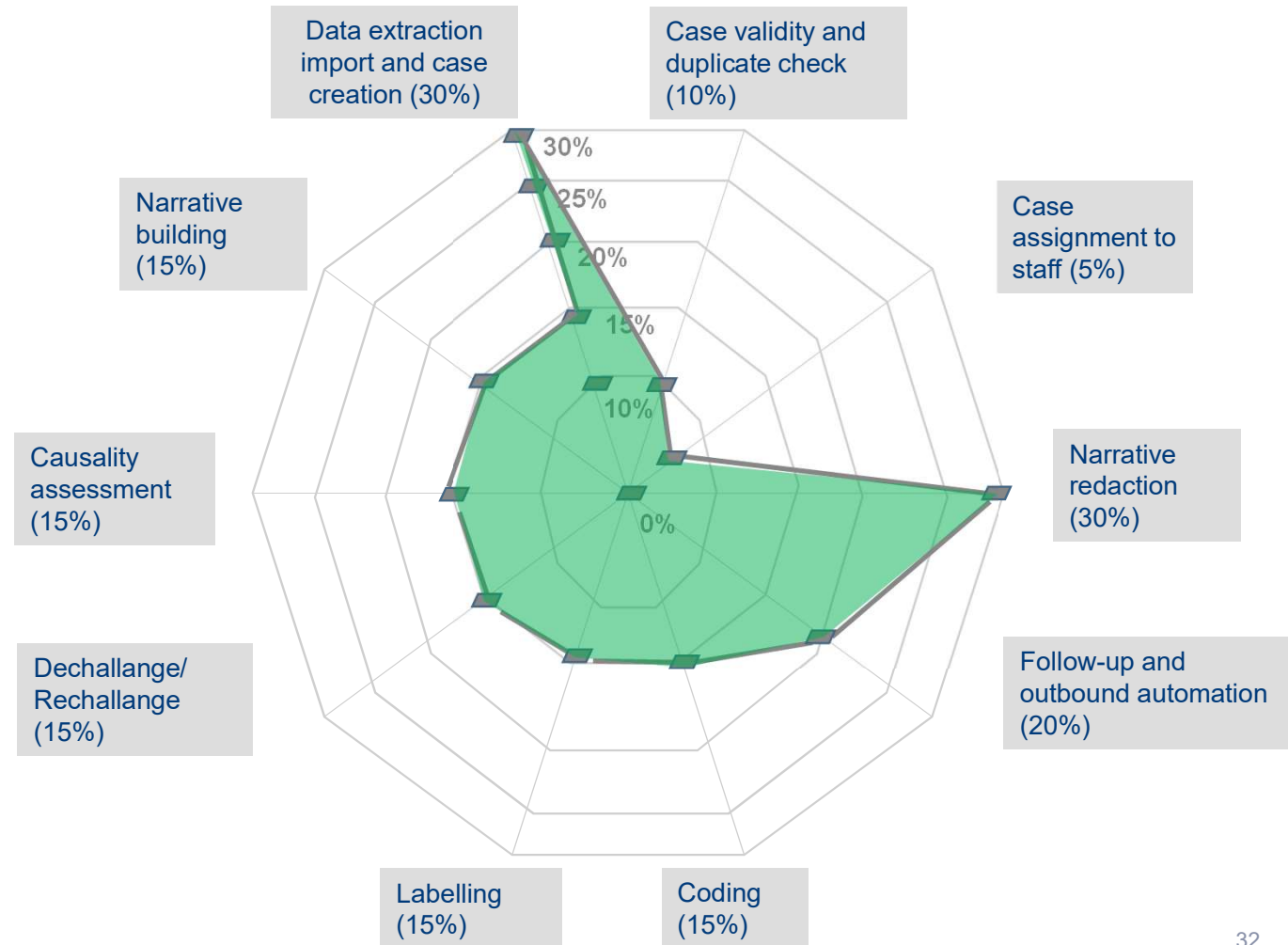
Medical Literature Monitoring & Automation



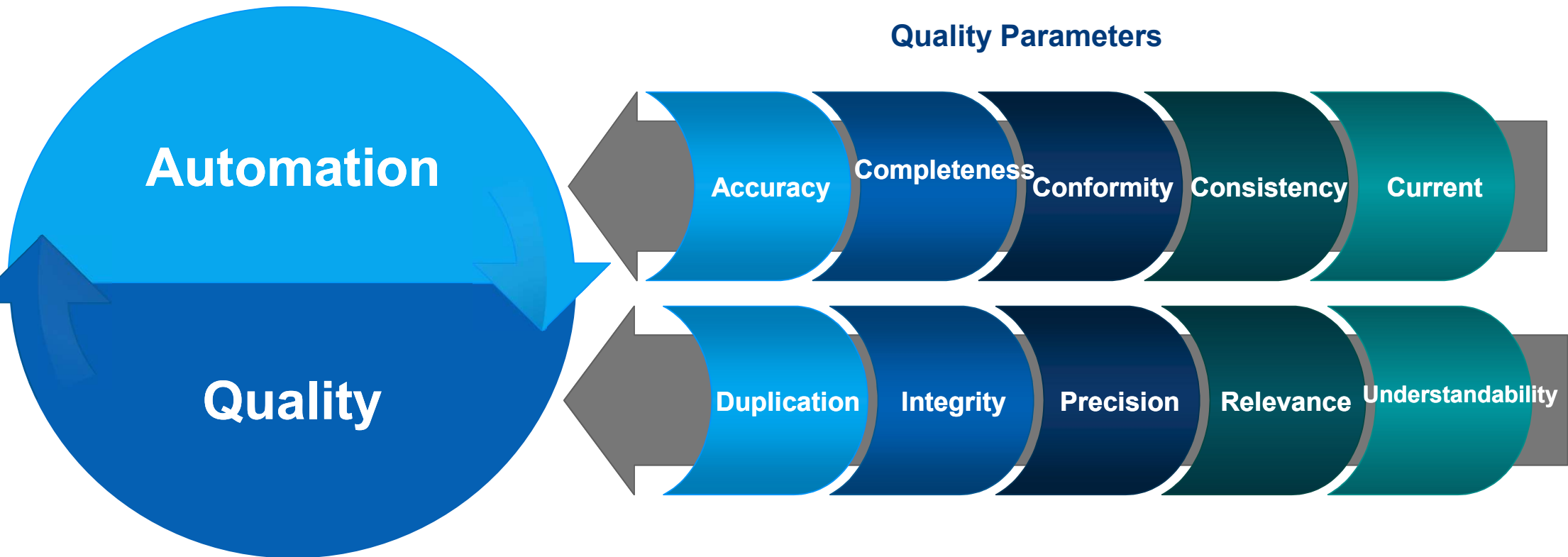
Expected Business Outcome of Automation

Automation - Productivity Gains

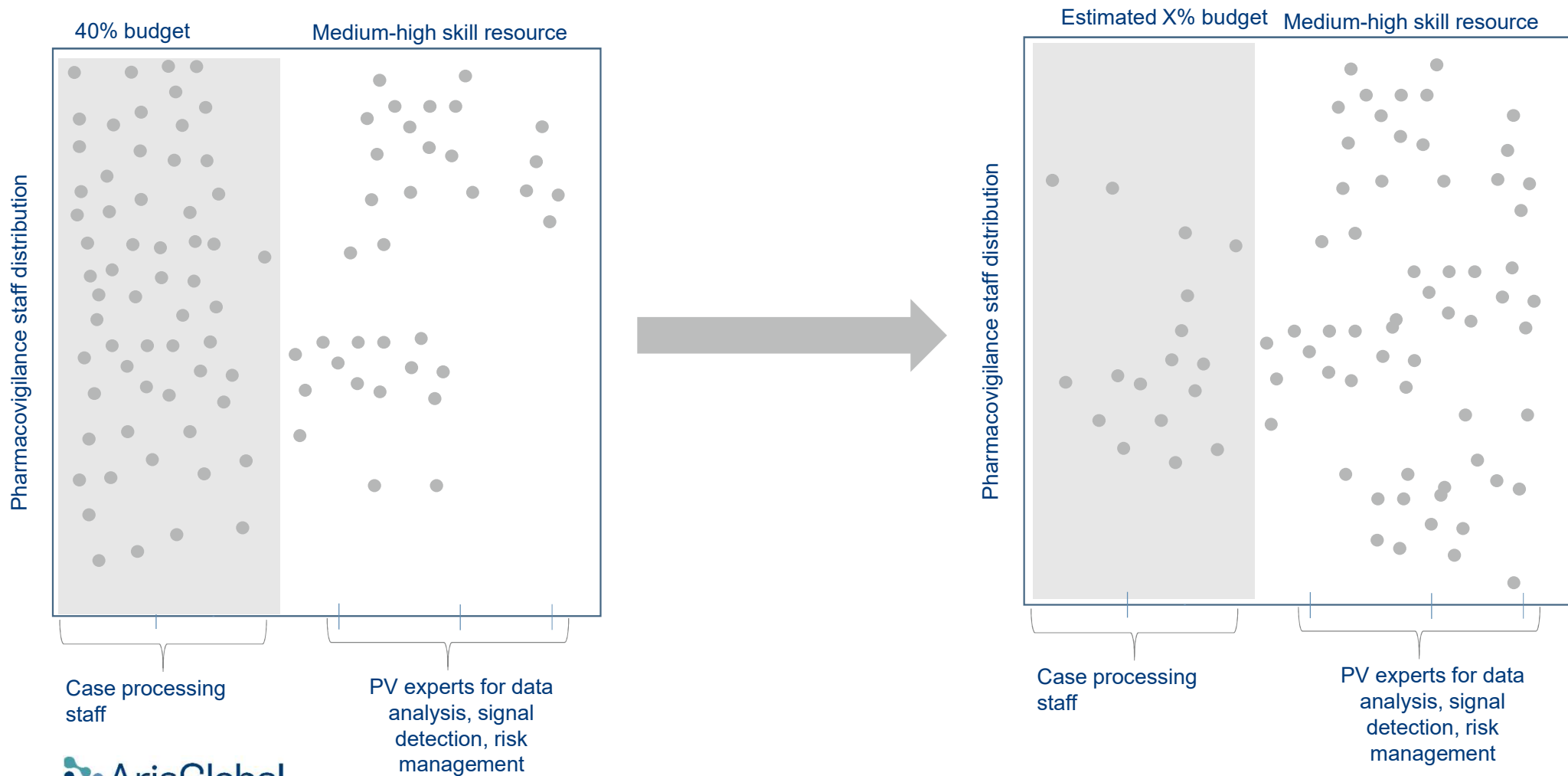
- Automation in case processing is expected to have significant productivity gains
- Up to 30% increase in productivity can be achieved in tasks such as narrative redaction
- An estimate of the gains in productivity that can be achieved through automation in case processing is presented here.



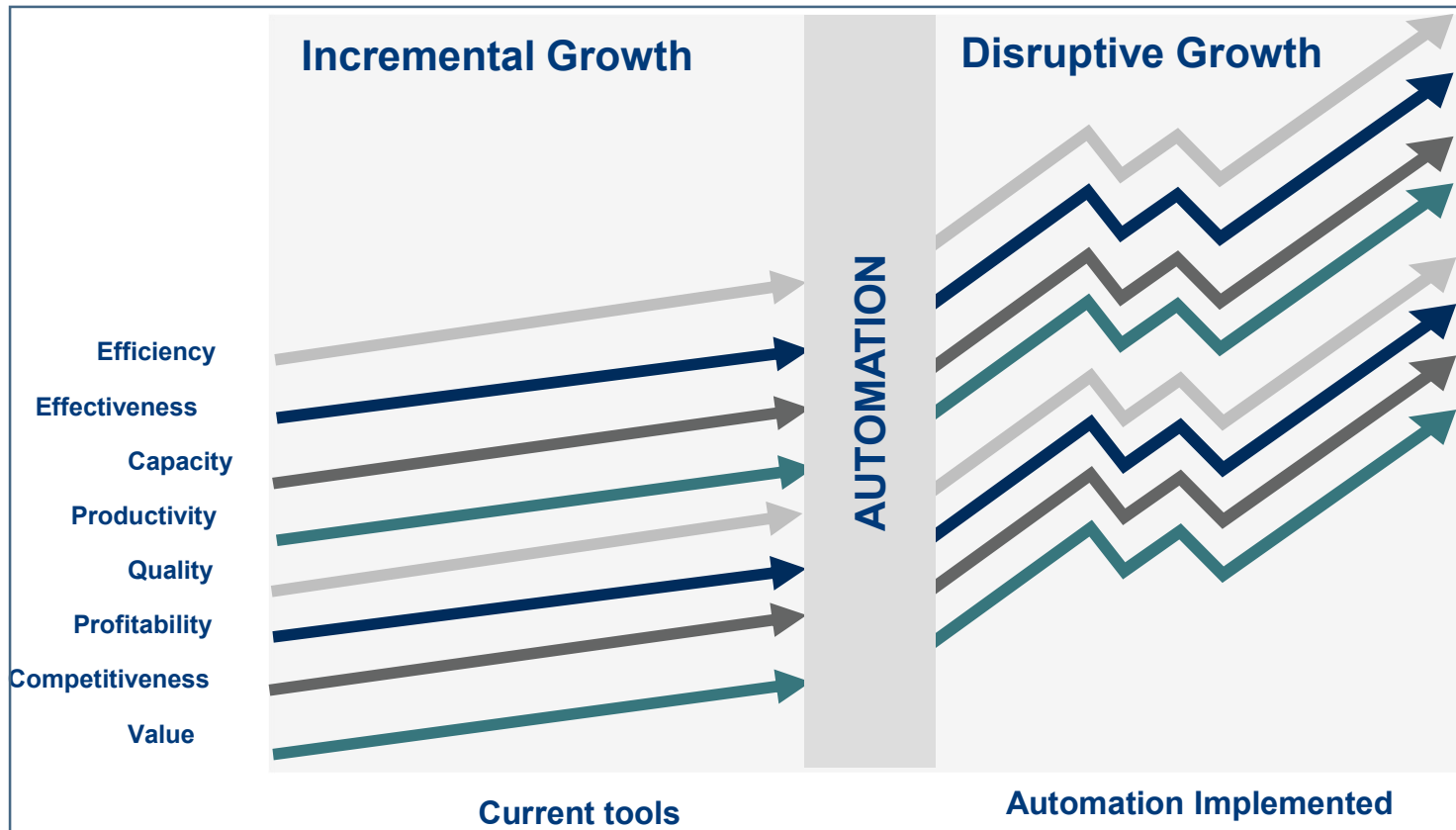
Automation-Impact on Quality



Automation- PV Resource Redistribution



Automation – Impact on Metrics



Automation leads to disruptive growth in performance

LifeSphere Cognitive Cloud Platform

Total Cost of Ownership

- SaaS solution eliminates costly internal infrastructure and support costs
- Annual upgrades and quarterly releases/updates included
- Standard ISP configuration reduces setup & implementation fees and facilitates seamless upgrades
- End-to-end product suite eliminates costs associated with multiple vendor offerings

Compliance

- Common technology stack for efficient, scalable and seamless data integration across ArisGlobal Life Sciences suite of products and other systems
- Facilitates compliance with data privacy and other industry/regulatory obligations
- Multi-tenant cloud architecture continuously delivers rapid innovation and ensures seamless updates

LifeSphere



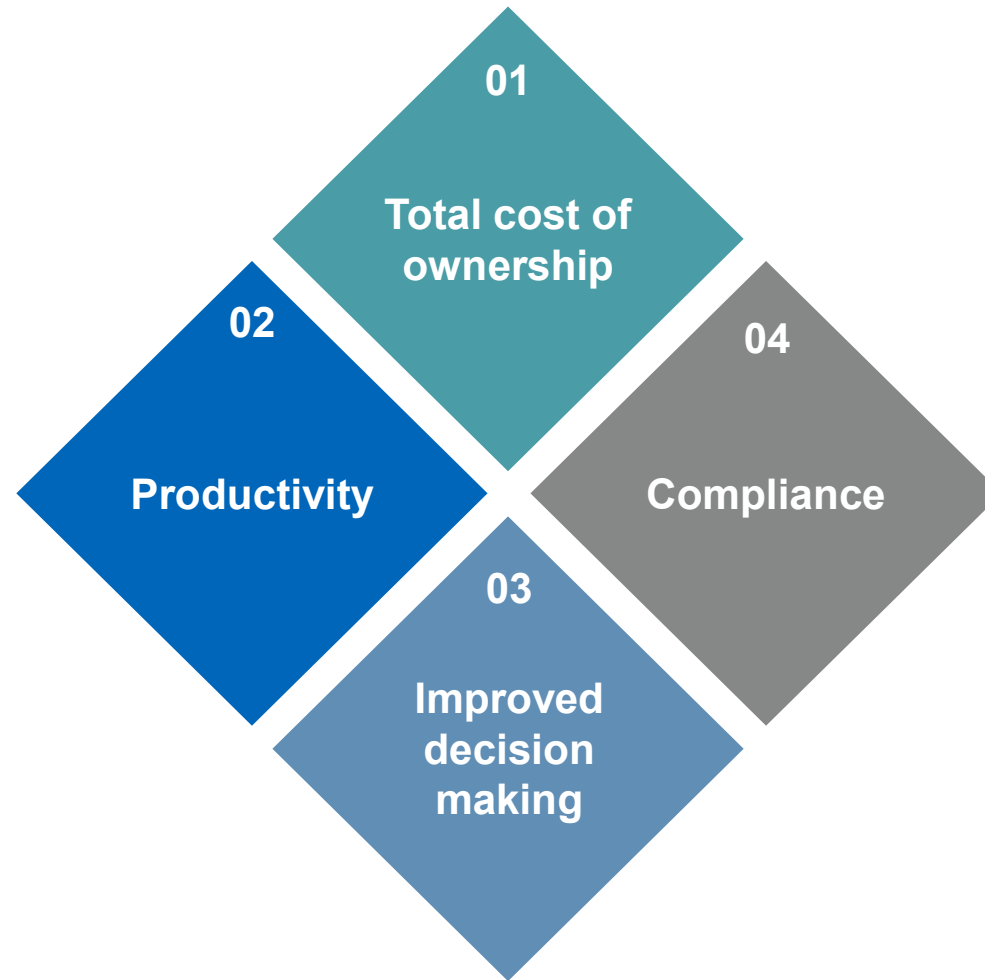
Productivity

- Embedded automation and cognitive computing for higher productivity
- Seamless integration eliminates redundancy between systems
- Embedded workflow and superior easy of use drives productivity

Quality

- Established QMS, leveraging over 30 years of experience with building regulatory compliant solutions for life sciences
- SOC 2 compliant
- ISO 27001 certified development

Benefits of LifeSphere Safety™



Thank You

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