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Efficiency gain in business models for global pharmacovigilance:- Automation and burying the silos

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Definitions in outsourcing

Outsourcing: Refers to the act of obtaining services from an external source.

- **Business process outsourcing (BPO): Management of a particular business process to a third party that specializes in the process. Major IT and consulting organizations**
- **Knowledge process outsourcing (KPO)/ Consultancy: Knowledge intensive; high-end work is outsourced to skilled and experienced professionals.**
- **Contract Research Organizations (CRO):- Similar to BPO; however DNA of the organization is more like Pharma.**

Outsourcing in PV-Boon or Bane

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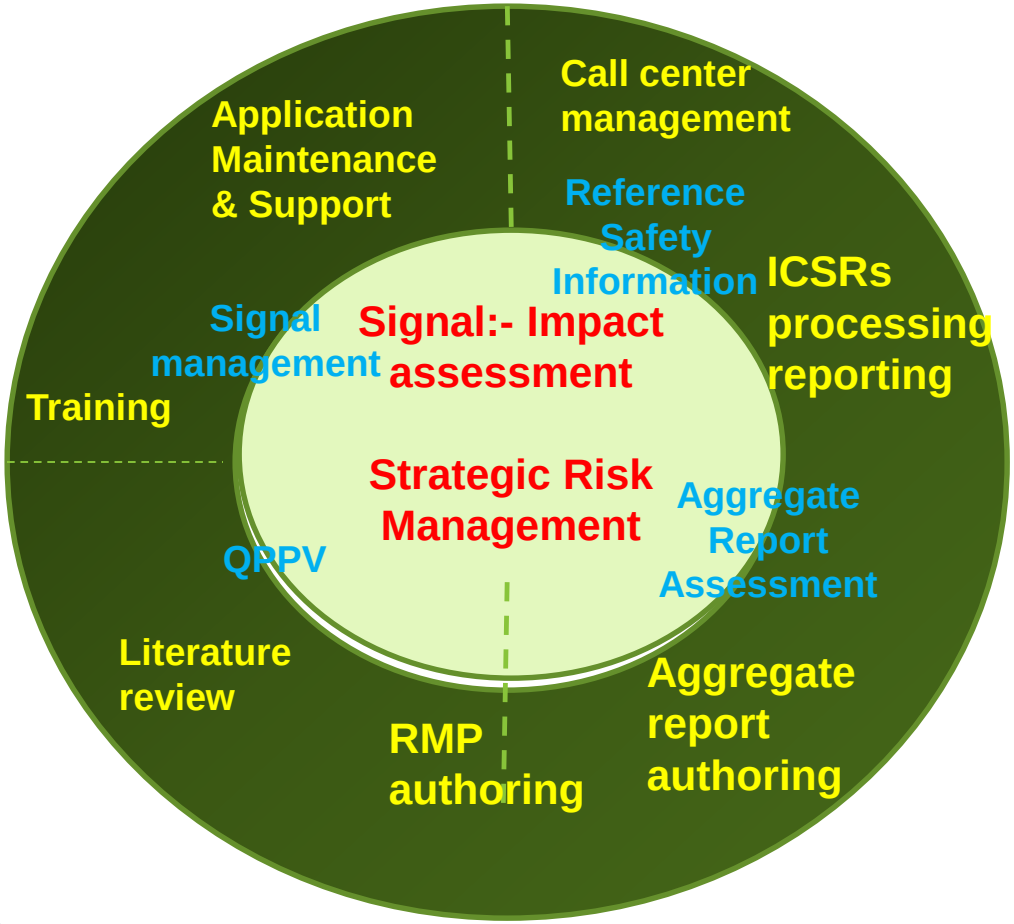
Internal sourcing

- PV personnel well-versed with overall safety profile
- High overheads; hence relatively cost inefficient
- Expensive human resource
- PV still considered as strategic liability

Outsourcing

- Wider experience across multiple interdisciplinary projects (sharing of best practices)
- Cost optimization
- Scalability can be easily attained
- Dependency on sponsor
- High attrition
- Extremely competitive

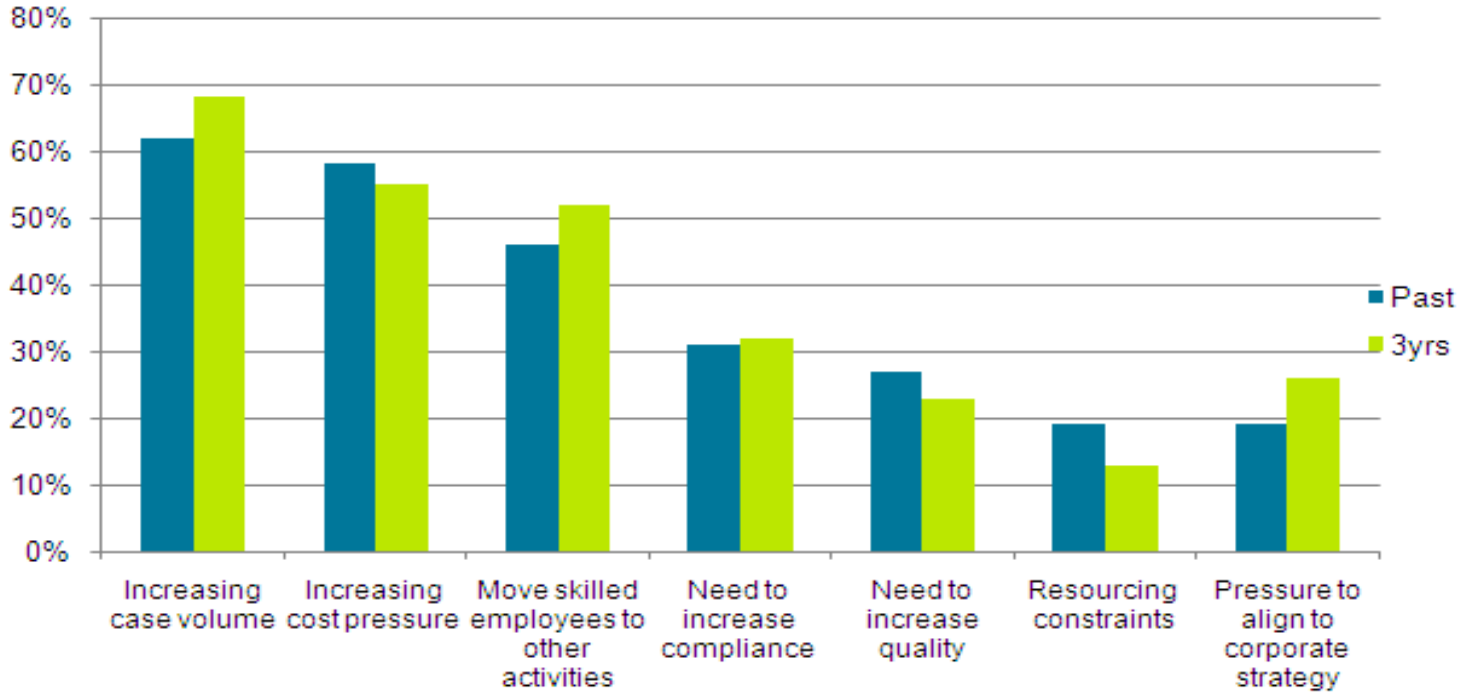
Parts of PV which are outsourced



Core PV Activities for Sponsor

Non- Core/PV Activities for Sponsor

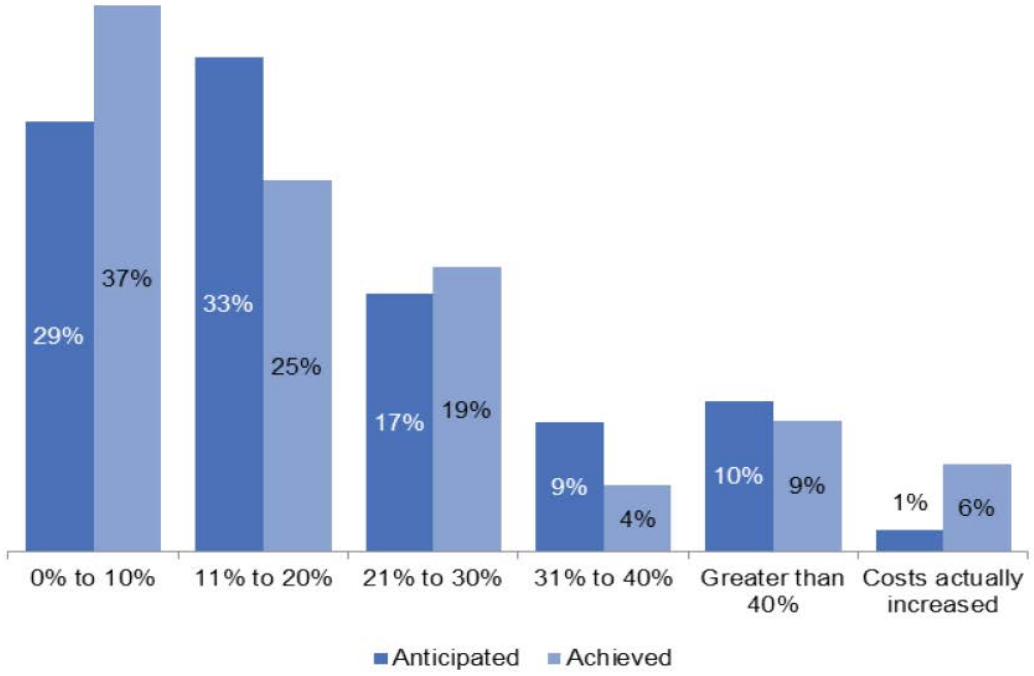
Drive to outsource



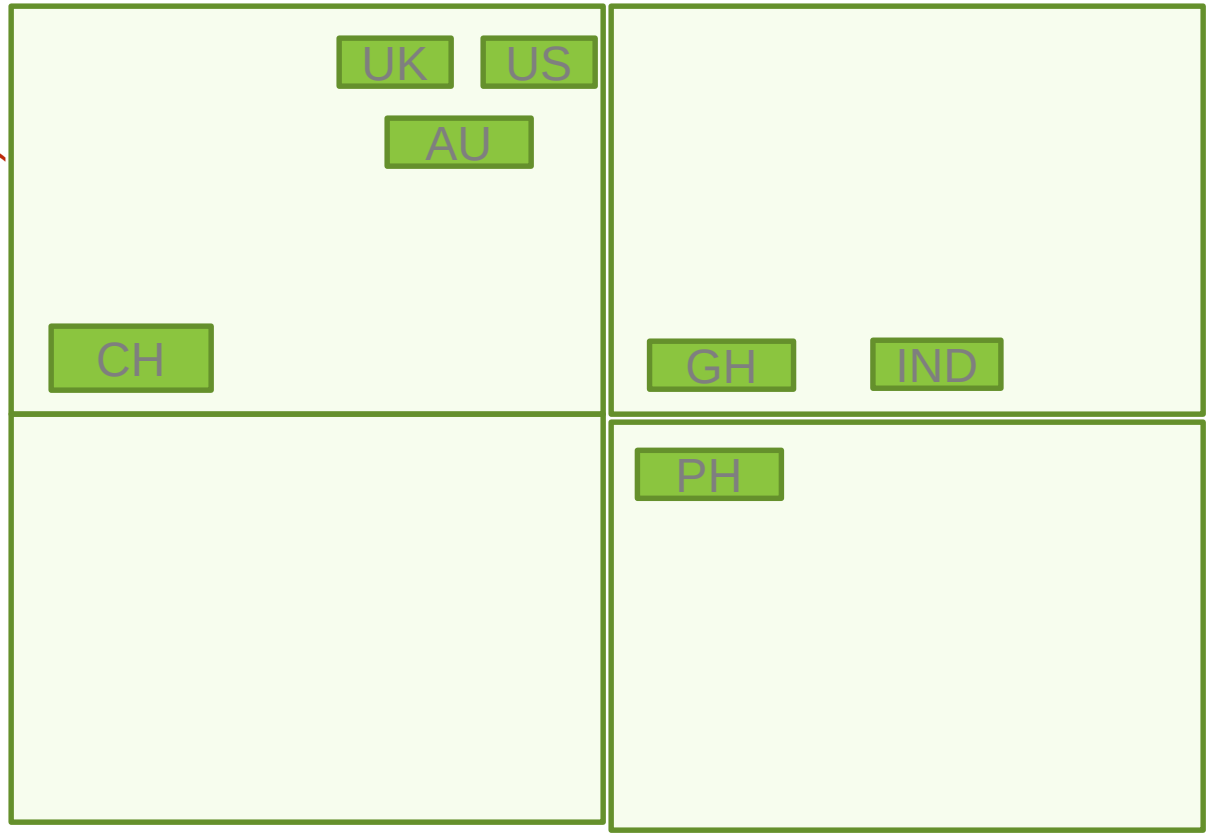
Source: WCI Consulting Survey 2012

Is outsourcing cheaper?

- **The Deloitte 2012 Global Outsourcing and Insourcing Survey found 57% of respondents (from 111 companies with $1 billion to $5 billion median revenue, and representing 22 primary industries) achieved cost savings of more than 10%.**

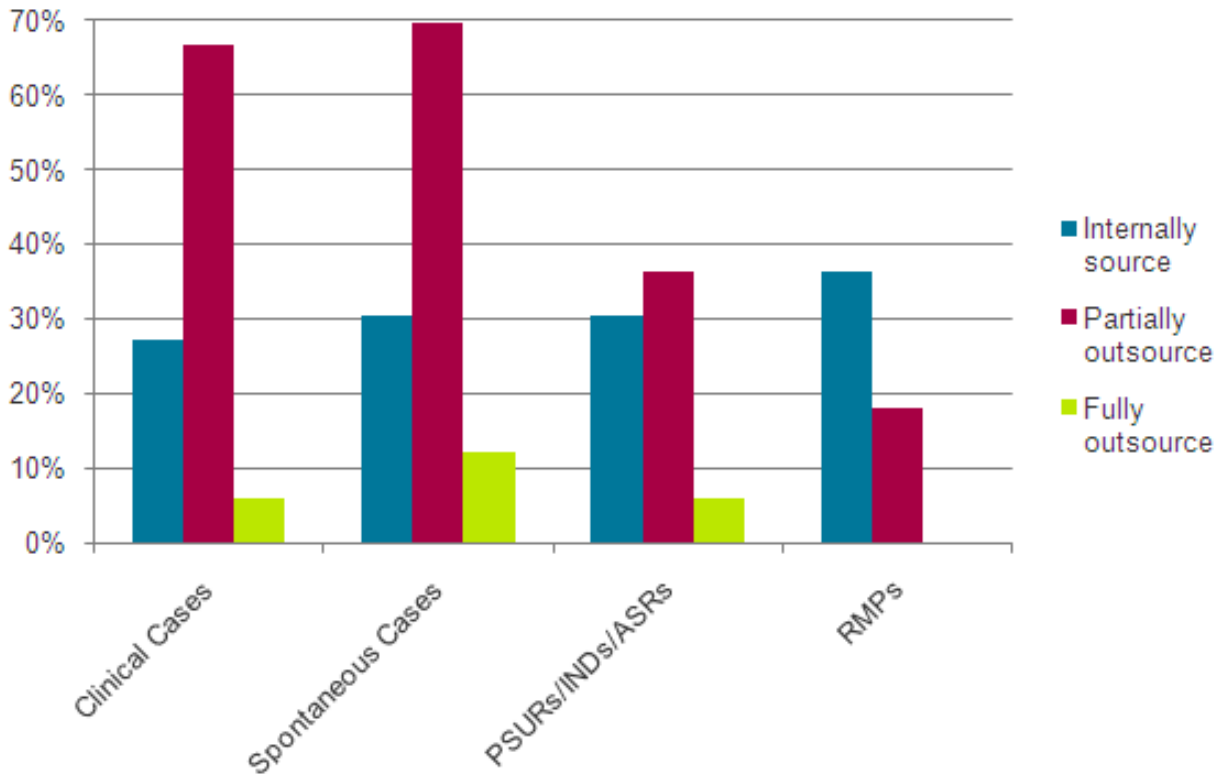


Location assessment



UK:- United Kingdom
US:- United States
AU:- Australia
CH:- China
IND:- India
PH:- Philippines
GH:- Ghana

Outsourcing: current status



Source: WCI Consulting Survey 2012

IntraScience survey 2016

%	Outsourcing activity (n=8)
80%	ICSRs
60%	Aggregate reports
50%	Surveillance
50%	Post-approval signal evaluation
50%	Regulatory interactions/documents
40%	Quality metrics/compliance
30%	Data housing

Outsourcing Model Comparison

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CRO

- Long-term relationship with pharma /biotech companies
- Brand value
- Availability of subject matter experts
- Greater synergy: PV and allied clinical services

BPO

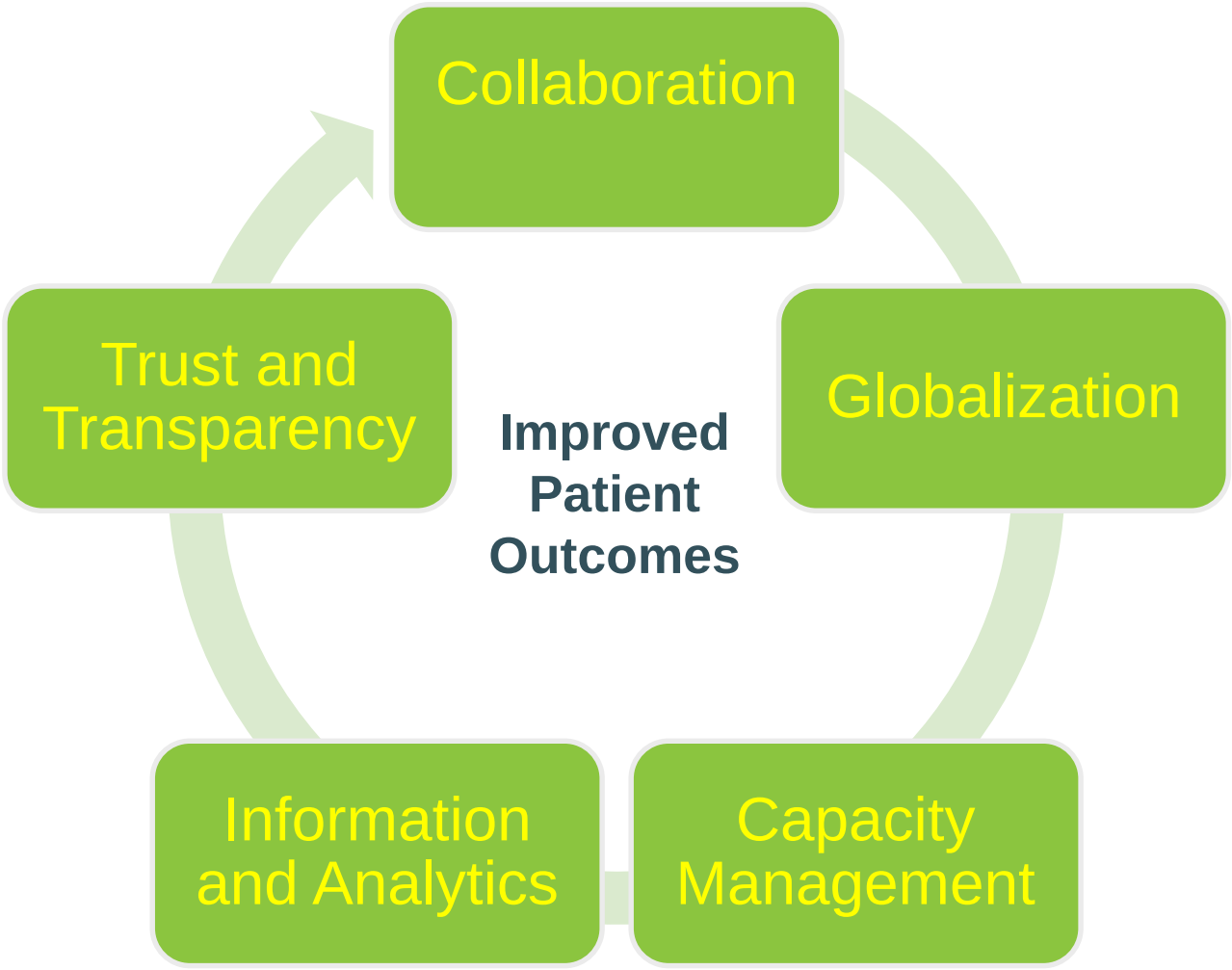
- Scalability
- Excellent governance models
- Professionals from multiple and varied domains and disciplines
- Strong IT backbone

Risks and Minimization/Prevention

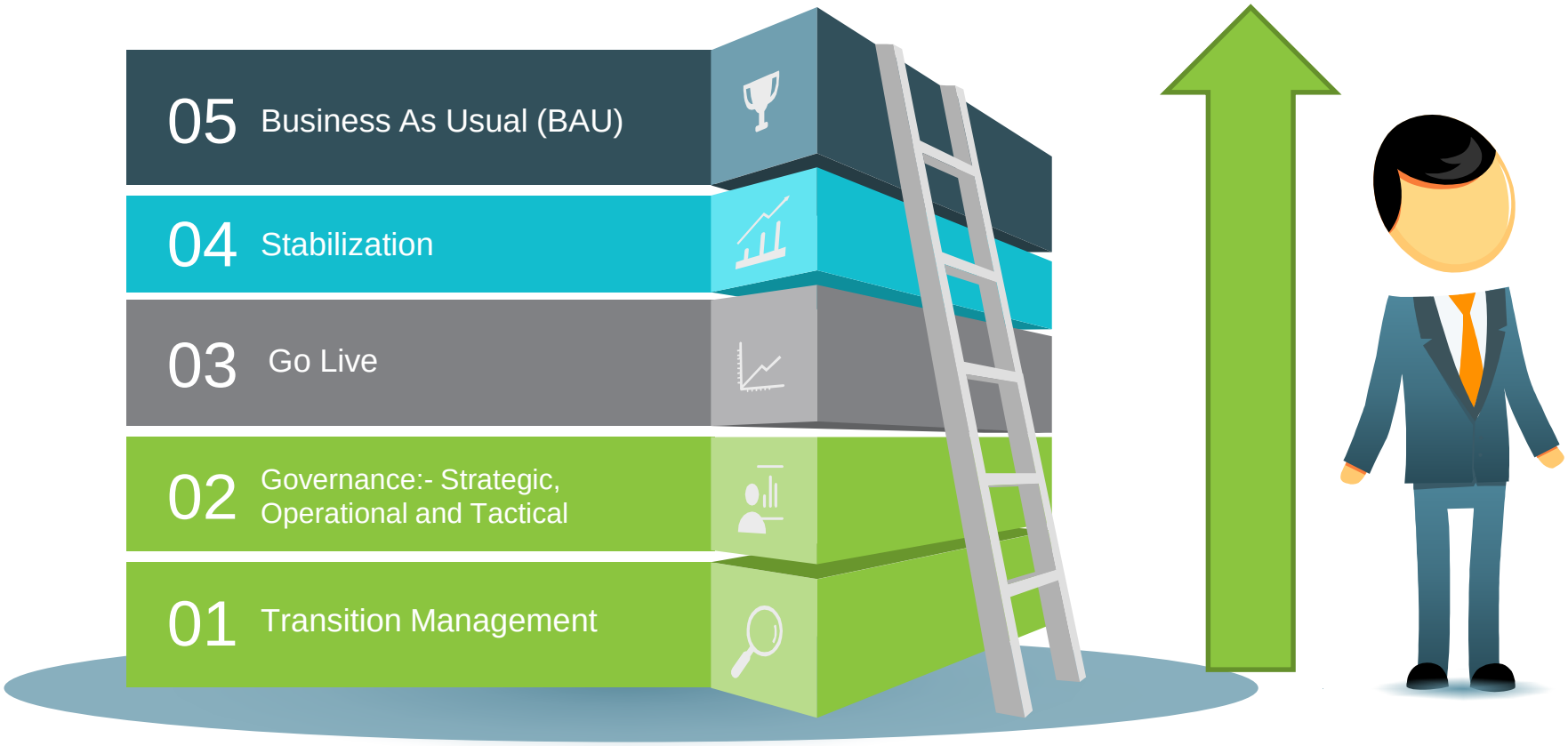
Risk	Minimization/ Mitigation
Quality and timelines adherence	Well defined SLAs (Service Level Agreements) Well defined metrics and dashboards
Data confidentiality and security issues	Well defined and implemented IT security policies. Audits
High attrition	Non compete agreements between the service providers. Better retention policies.
Dependency on Sponsor	Focus on partnership/ relationship building
Disaster and service disruption	Business process continuity and disaster management plans
Matrix environment	Well defined communication and escalation plans. RACI implementation

PV Business Outsourcing “Sutra”

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BSGGT model for Effective outsourcing Management

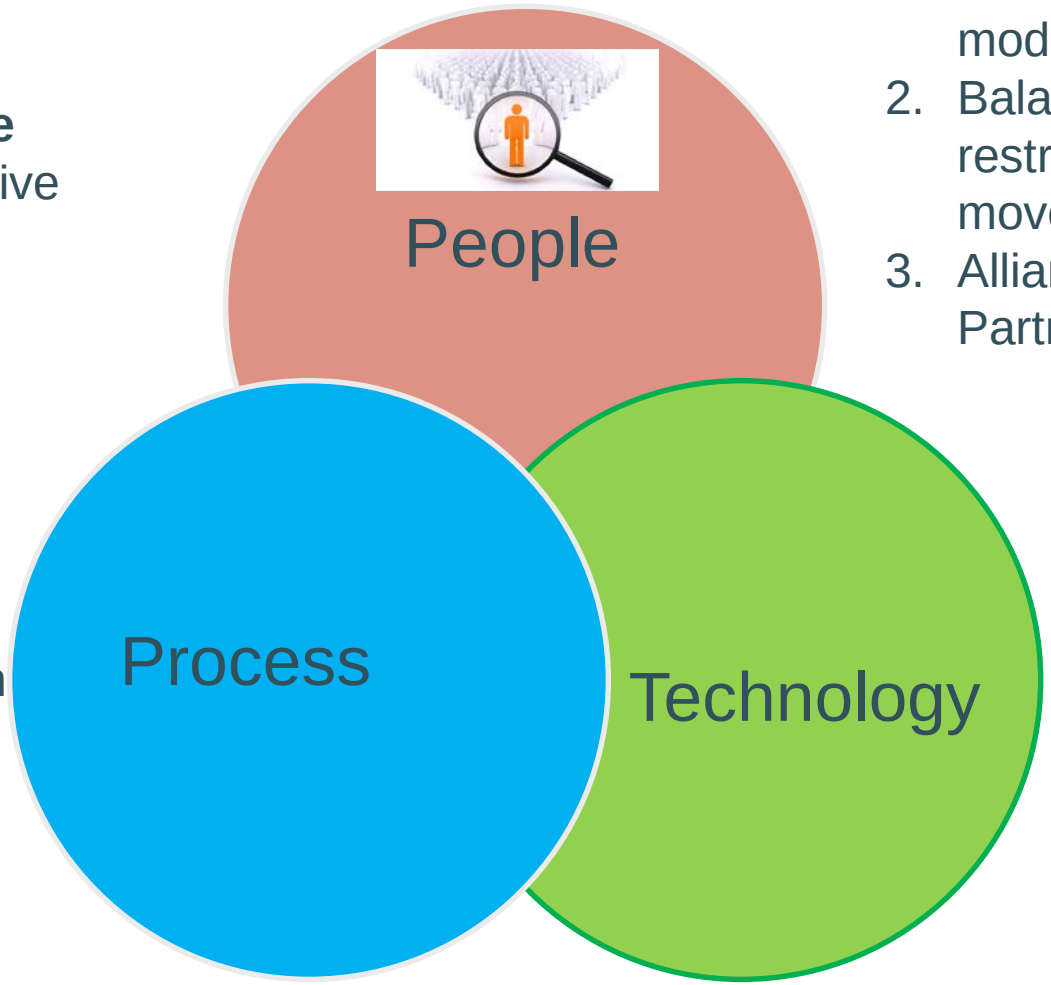


Adaptive PV Model

Survival of the Fittest:- Adaptive Intelligence



1. Lean and Mean
2. Re-engineer
3. Change Management



1. Flexible resourcing model
2. Balanced non-restrictive people movement
3. Alliances and Partnerships

1. End to end automation
2. Breaking silos e.g. clinical and post marketing
3. Embracing disruptive technologies

Trigger for Adaptive PV Model

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Tipping point for Traditional PV Business Models:

- Portfolio growth
- Increasing global footprint
- Ever changing regulatory landscape
- Collaboration between regulators
- Increased mergers and acquisitions
- Dwindling pipeline: cost pressure to align resources

Adaptive PV Model: Salient Features

- Demand for increased operational efficiencies
- Flexible resourcing model
- Proactive and prompt communication
- Outcome based evaluation
- Automation and bridging the silos
- Big data: managing signal to noise?

Adaptive PV Model: People Evolution

- **Flexible Resourcing Model:**
  - Scalability, Reproducibility and Consistency, e.g. case volume fluctuations
  - Spreading the “Pockets” of expertise



- **Balanced Non-restrictive People movement**

- **Alliances and Partnerships:**
- Long term strategic partnership wherever possible



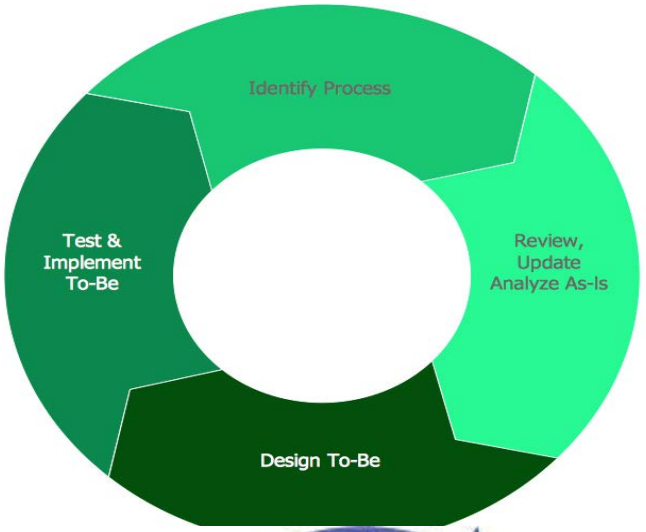
Adaptive PV Model: Technology Evolution

- **End to end automation:**
  - Getting “out of comfort zone” e.g. Mobile app direct AE reporting technology, NLP
- **End to end integration:**
  - Breaking silos
  - “Cradle to Grave” approach for product safety
  - Real world evidence dataset
  - Seamless tracking from AE to signal to risk to impact to effectiveness of risk minimization action plan
- **Embracing disruptive technologies:**
  - Mobility
  - Next Generation Predictive Analytics

Adaptive PV Model: Process Evolution

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- **Lean and Mean**
  - End to end PV services: PV in Capsule



- **Re-engineer**
  - Look beyond “Transactional” process



- **Effective Change Management**



Case Intake- Prevailing Challenges

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$8 Bn
Spend annually on call centre infrastructure

~60%
AEs reported through call centres

20 to 30
Minutes per AE call

30%
Call volume for follow-ups
(outcome/ unavailable/ missed information)

15%
Data capture error rates in spite of peer-review

Source: QuarterWatch Report - Institute for Safe Medication Practices, Indegene internal primary research



Highly repetitive and manual tasks



Redundant processes result in ineffective data capture



Non-optimized call flow and inefficient follow-ups

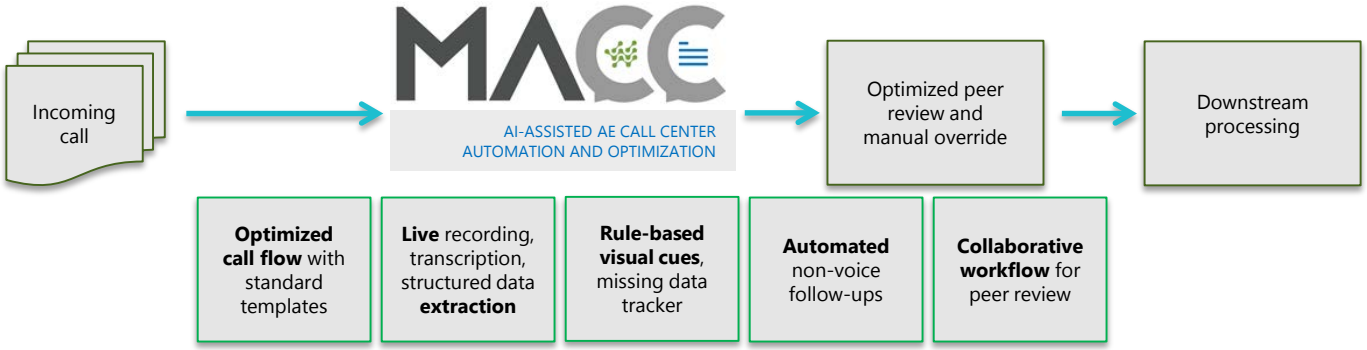
Nature of current safety processes lends to:

Low data quality. **High inefficiencies.**

Case Intake:- Driving Automation

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Intelligent call flow assistance with automated data capture and review processes to enable quicker, more accurate and noise-free case intake



Impactful Outcomes

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	Current	Interim (6-12 months)	Steady-State (Beyond 12 months)
Review Efforts	**100%** manual review	**40%** reduction in review efforts	**60%** reduction in review efforts
Accuracy	**15%** Data capture error rates	**>99%** data quality	**100%** data accuracy and relevancy
Processing Time	**20 to 30 mins** AE call processing time	**18 mins** AE call processing time	**13 mins** AE call processing time
Call Volumes		**10%** reduction in follow-up calls	**20%** reduction in follow-up calls
Cost Savings		**25%** cost savings annually	**>50%** cost savings annually

Case Processing:- Prevailing Challenges

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<60%
compliance rate across case processing continuum

10%
of SAEs not submitted within timelines

30%
of skilled manpower deployed for manual Data Entry

~40%
of errors creep during Case Intake/ processing

~80%
of errors are typographical and missed data points

Source: http://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2398401, Indegene internal analysis based on prior engagements



Multiple source document formats



Highly repetitive and manual tasks



Human intensive process activities

Nature of current safety processes lends to:

Significant errors. **Low compliance levels.**

Case Processing:- Indegene Experience

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Medical/ Scientific/ Clinical application through human intervention and AI-NLP-ML are crucial to surmount Compliance and Productivity challenges

Indegene Real-World Experience

ICSR Period	Total Volume for QA
18 Months	~3500

- Global Top 10 pharma was facing quality issues in case processing with their existing vendors
- Indegene partnered with the pharma client as prospective QA partner for the ICSR samples, on a monthly basis
- QA activities for single case processing included: SOP compliance, reviewing all sources documents, verification of case receipt and case creation date

45% of cases had Data Entry errors

31% of cases had QC Errors

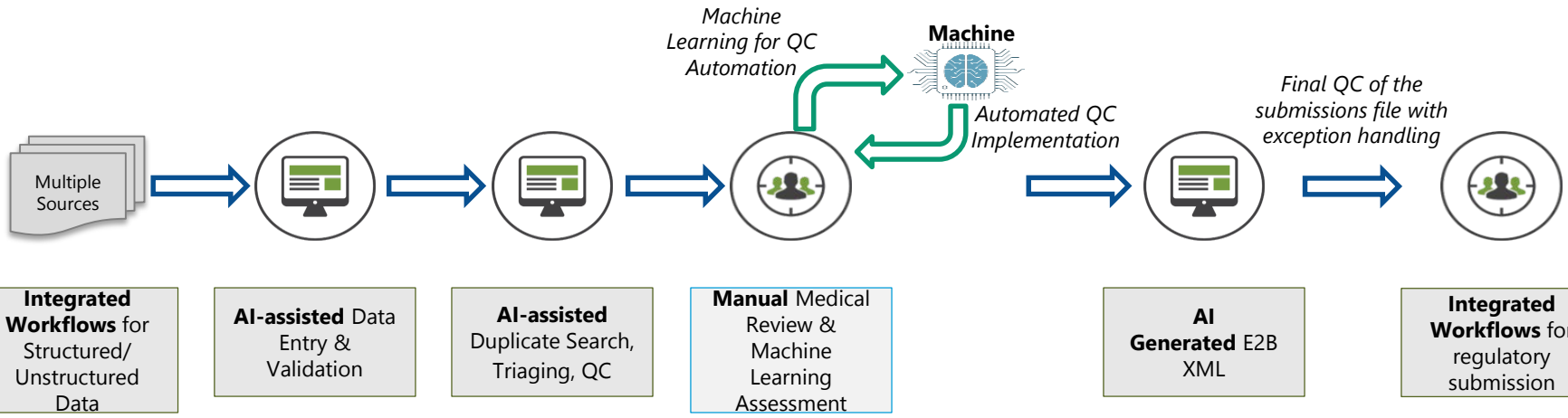
33% of errors were product related, followed by **28%** errors in the event narratives

36% were major findings which could impact Regulatory compliance and quality of medical assessment

Source: Indegene Data

Case Processing:- Driving Transformation

Automate case processing through medically trained AI
with perfect data quality in the shortest possible time,
no matter the type, language or format of source documents.



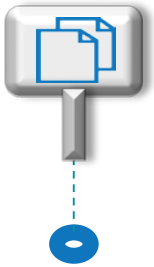
Case Processing:- Outcomes

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	Current	Interim (6-12 months)	Steady-State (Beyond 12 months)
Compliance	**60%** timeline compliance	**100%** timeline compliance	**100%** timeline compliance
Accuracy	**40%** data errors	**>99%** accuracy	**>99%** accuracy
Processing Time	**70 mins** case processing time	**50 mins** case processing time	**30 mins** case processing time
Automation		**25%** reduction manual intervention	**55%** reduction manual intervention
Cost Savings		**25%** cost savings across case processing	**>50%** cost savings across case processing

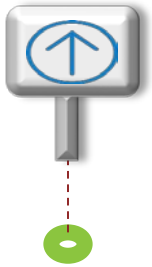
Case Processing:- Implementation

Start small. Start strong.
Non-critical/ non-sensitive product(s) to prove the concept.



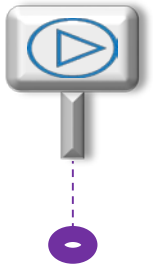
Primer
0-3 months

Prime the machine with client-specific data, run tests, monitor tests, tweak approaches



Pilot
6-12 months

Roll out for a specific area and monitor performance and outcomes



Deploy
Beyond 12 months

Enterprise-wise deployment

THANK YOU FOR YOUR KIND ATTENTION

