Data and Compliance — Mitigating the Risk of Government Enforcement, Individual Liability, and Corporate Integrity Agreements through Analytics

November 6, 2019

Building a better working world

Today’s agenda

Overview

- Common Challenges for Global Companies
  - Insights from EY's Analytics Survey
- Mitigating Risk through Analytics
- How to Design a Successful Data and Analytics Program
- Case study and Q&A

Today’s Challenges for Global Companies

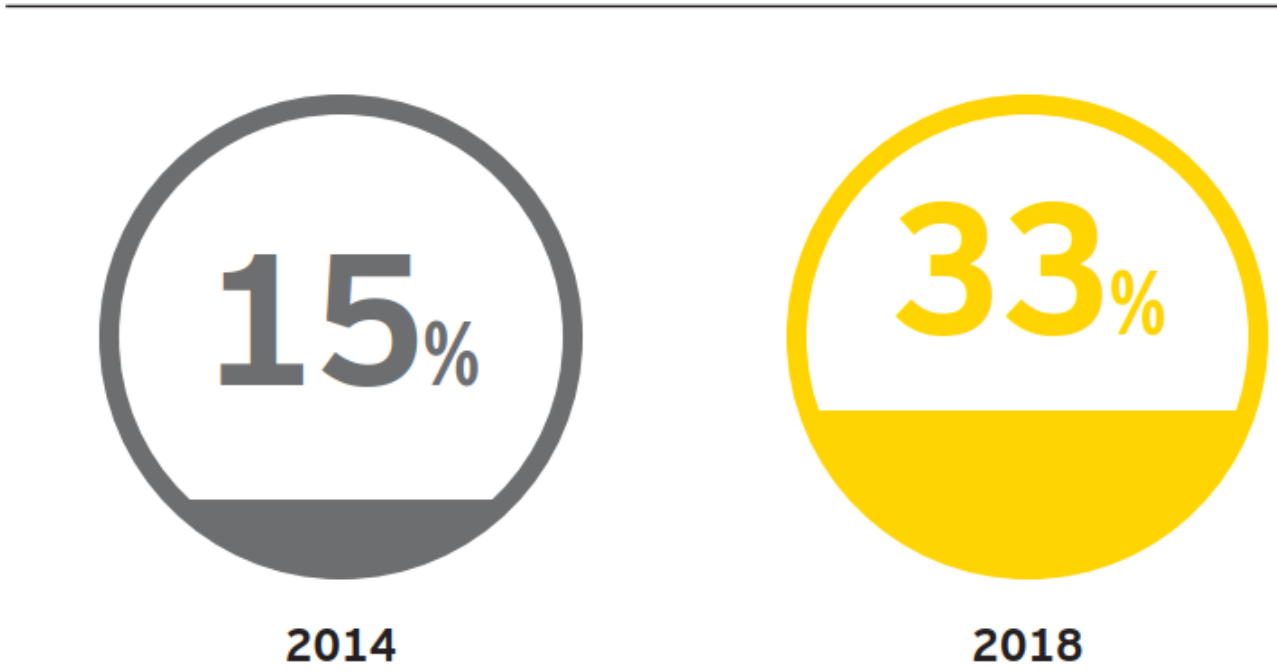
Common Challenges for Global Companies

- The greatest growth is in emerging markets
  - Legal risks are highest in these markets
  - National laws and prosecution priorities are evolving
  - Public expectations of business integrity are increasing
- Acquisitions and joint ventures have hidden risks
  - Business practices may become apparent only *after* the acquisition
  - Business cultures are difficult to influence from afar
- Dispersed locations stretch legal, audit and compliance resources
- Risks must be managed across sales channels, supply chains and third-party relationships
- Prosecutors enforce laws across borders

Observations on current challenges being addressed by many Compliance Officers

- Compliance risk assessment is not robust
  - Moving away from relying on surveys and forms being completed
  - Adding facilitated sessions and interviews in high-risk locations (rotating schedule)
- Policy management is lacking
  - Moving toward clear standards for policy development, maintenance, review, and deletion
- No common view of compliance program elements needed across various compliance risk areas
  - Establishing compliance frameworks that set forth core elements that must exist for each compliance risk area in the company (process for intake of new laws, roles for policy development, processes for monitoring and reporting
- The compliance officer does not have all relevant information in a timely manner
  - Establishing escalation guidelines to ensure potential issues of non-compliance (meeting a certain threshold) are communicated to the compliance officer – no matter the source of the information
- Third-party due diligence is not robust
- Inconsistent investigation practices
  - Establishing investigation protocols and standards and core training for investigators
  - Centralized, if possible, case management system for all investigations

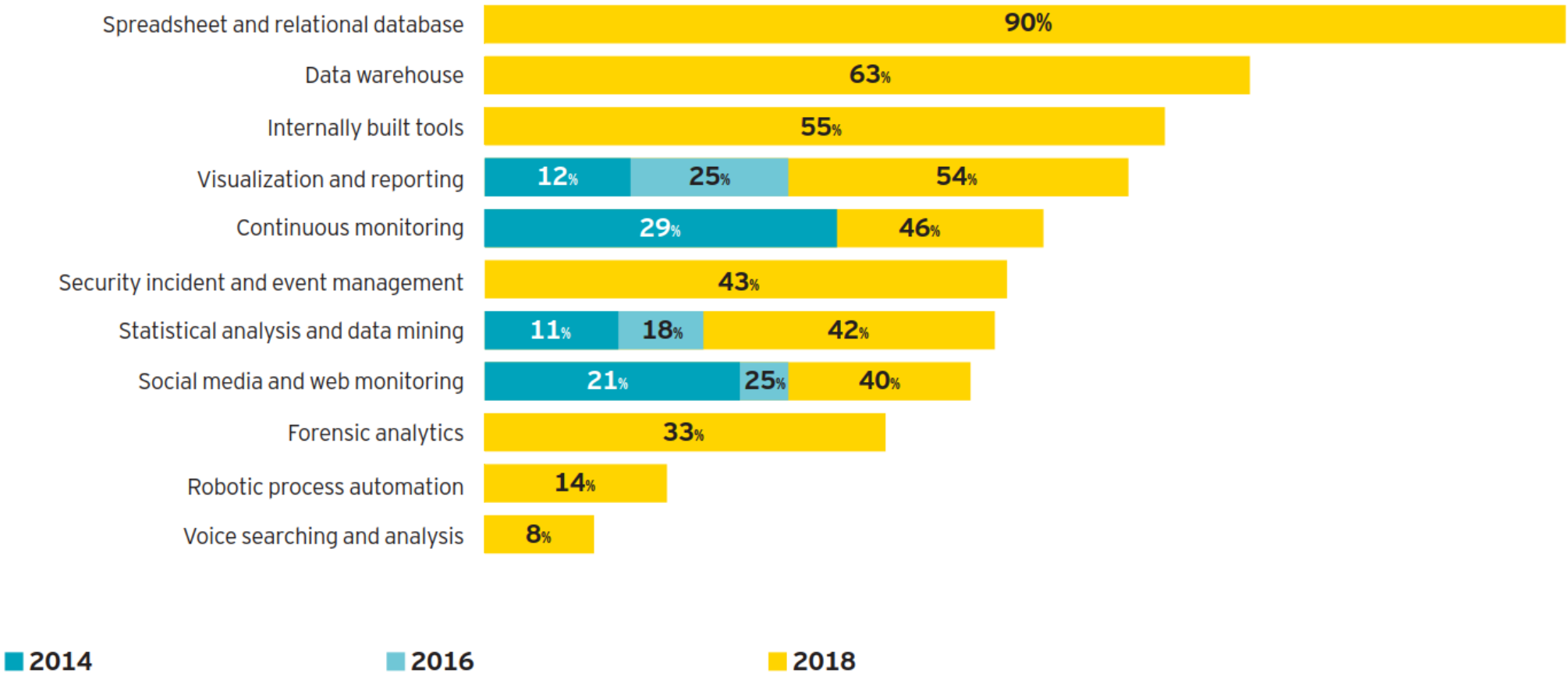
Insights from EY's 2018 Forensic Data Analytics Survey



Challenges in combining or accessing data sources

Q: Which do you consider to be the main challenges that you face with respect to FDA?
Base: all respondents (745)

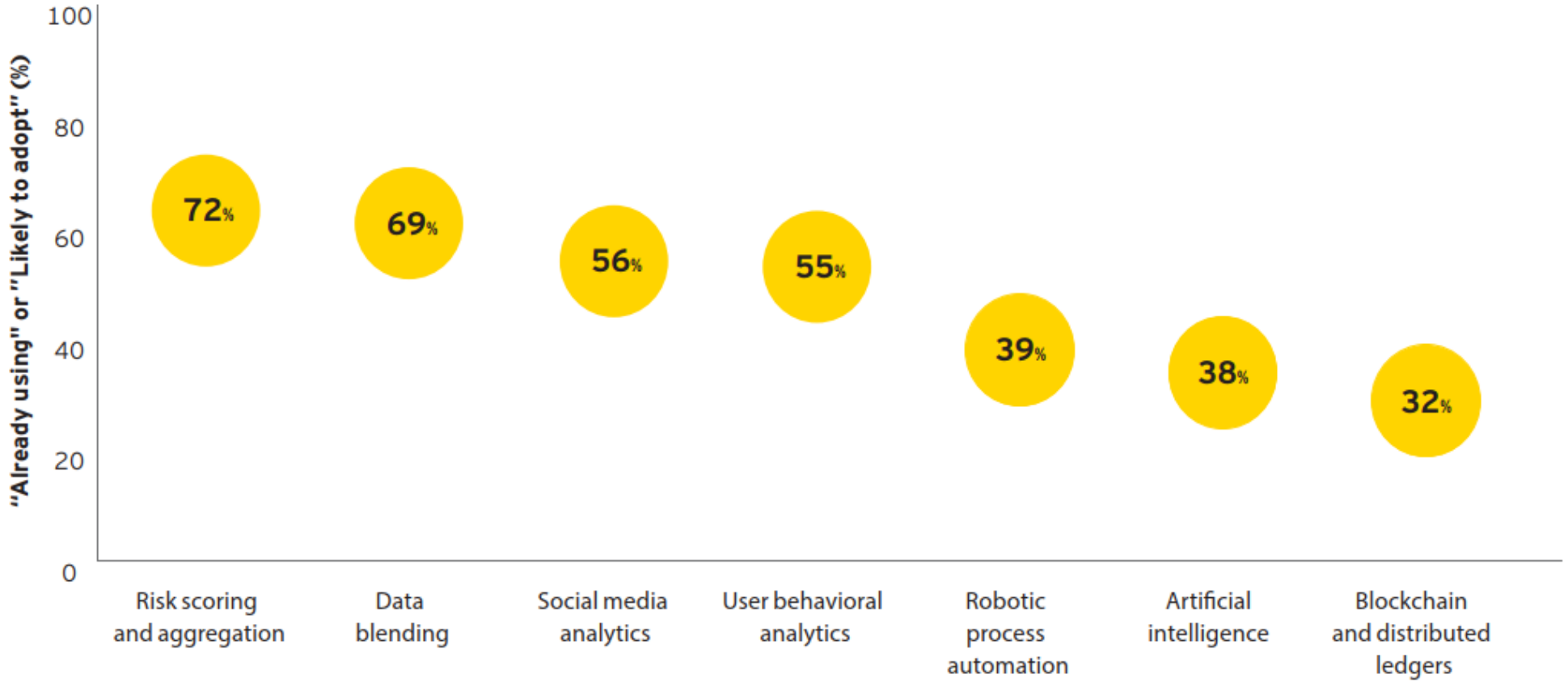
FDA Survey: Current Technologies



Q: In the context of managing your legal, compliance and fraud risks, what FDA technologies do you utilize?
Base: all respondents (745)

FDA Survey: Emerging technologies

Figure 5: Future adoption of emerging FDA technologies and techniques

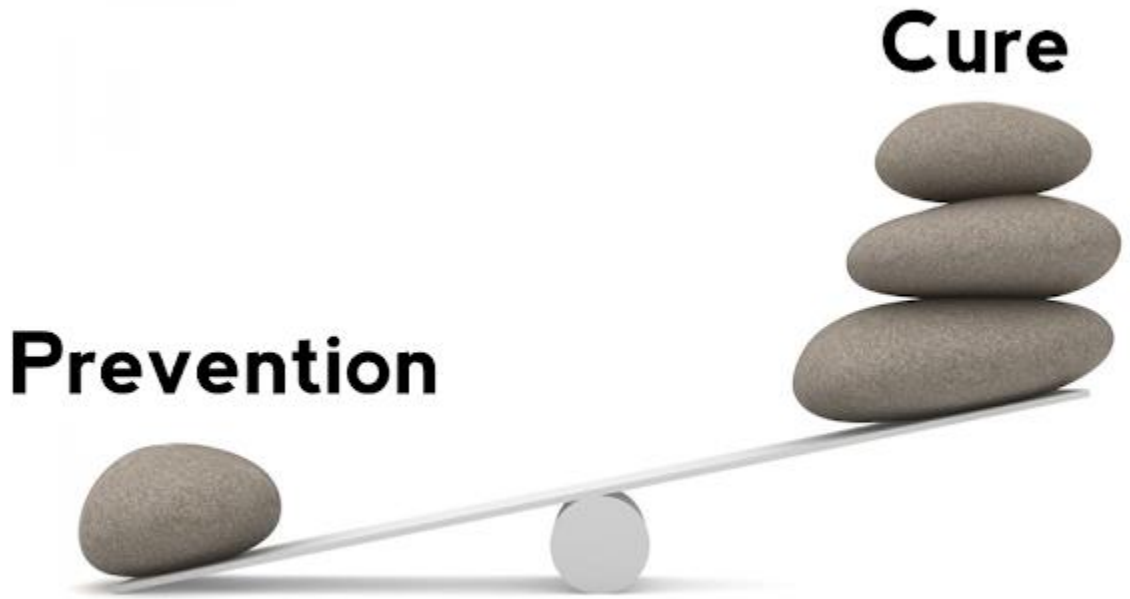


Q: **How likely is your organization to adopt these technologies and techniques within the next year?**
Base: all respondents (745)

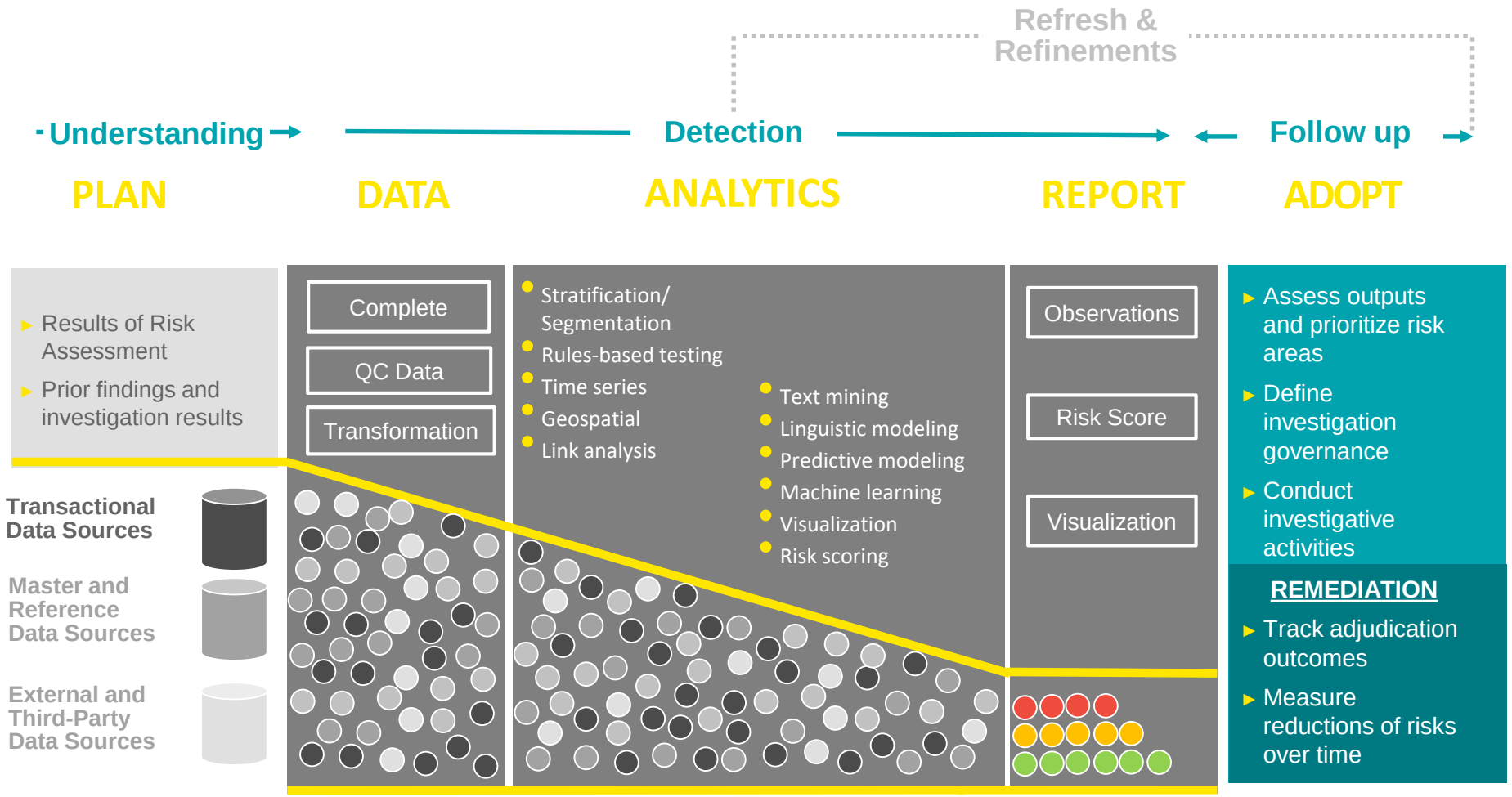
The Best Way to Mitigate Risk…

"An ounce of prevention is worth a pound of cure"

-Benjamin Franklin



How to Design a Successful Data and Analytics Program



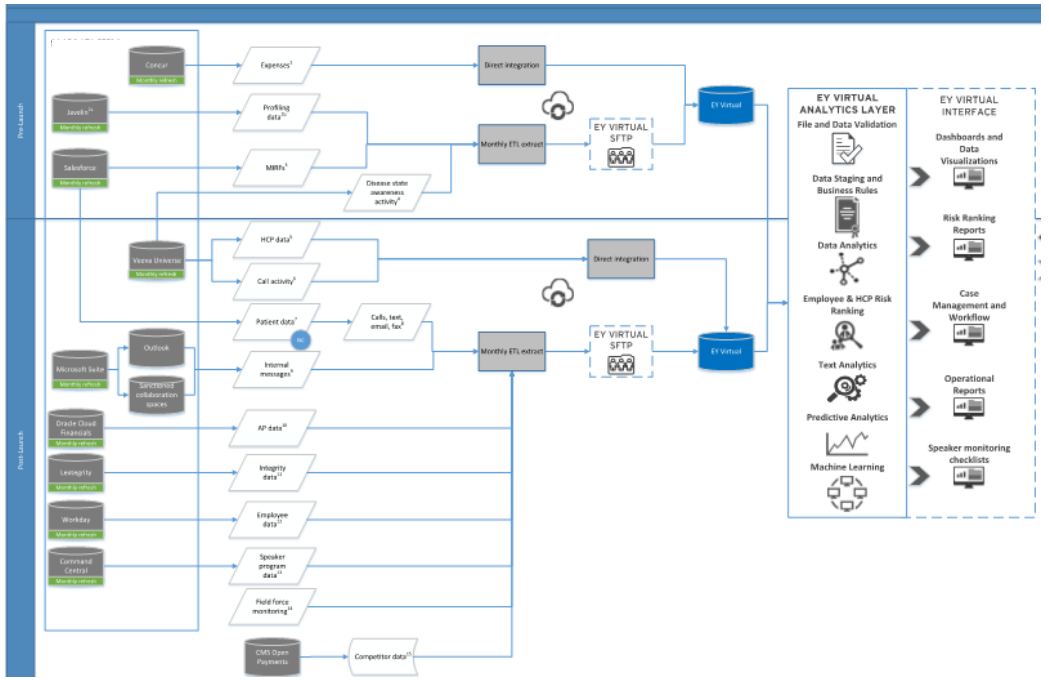
Phase 1: Planning

- Working session with all stakeholders (Compliance, Business, IT, etc…)
  - Identification of top risks
  - Agreement on governance
- Design a roadmap that incorporates short and long term vision
- Define KPIs to measure success
    - Risk reduction (risk scores over time, case outcomes, etc…)
    - Coverage metrics (cost of monitoring, time to close cases, risk areas covered, etc…)
    - Effectiveness of monitoring (Test results, speed to monitor, targetedness, etc…)
- Build the review workflow and methodology for consistency
  - Will case management be automated?
- Training materials and desktop manuals
- Keeping in mind common pitfalls:
    - Slow adoption
    - IT challenges
    - Noise in data/complex business rules
- Typical outputs for this phase:
  - Functional requirements document
  - Methodology and training docs

Phase 2: Data Management

- Understand the business rules before data
  - For example: how are distributor discounts calculated?
  - Work with the business to translate this into the data
- Mapping data sources into a common data model
  - Source systems vs. data warehouses
- Design data feeds
  - Flexibility for disparate refresh cadences
  - Scalability for future IT transformations
  - Acceptance of multiple input methods (APIs, RPA, manual uploads, etc…)
- Completeness and accuracy checks
  - Supervised vs. unsupervised

- Typical outputs:
  - Technical requirements documentation
  - Data maps and workflow diagrams
  - Data decision log

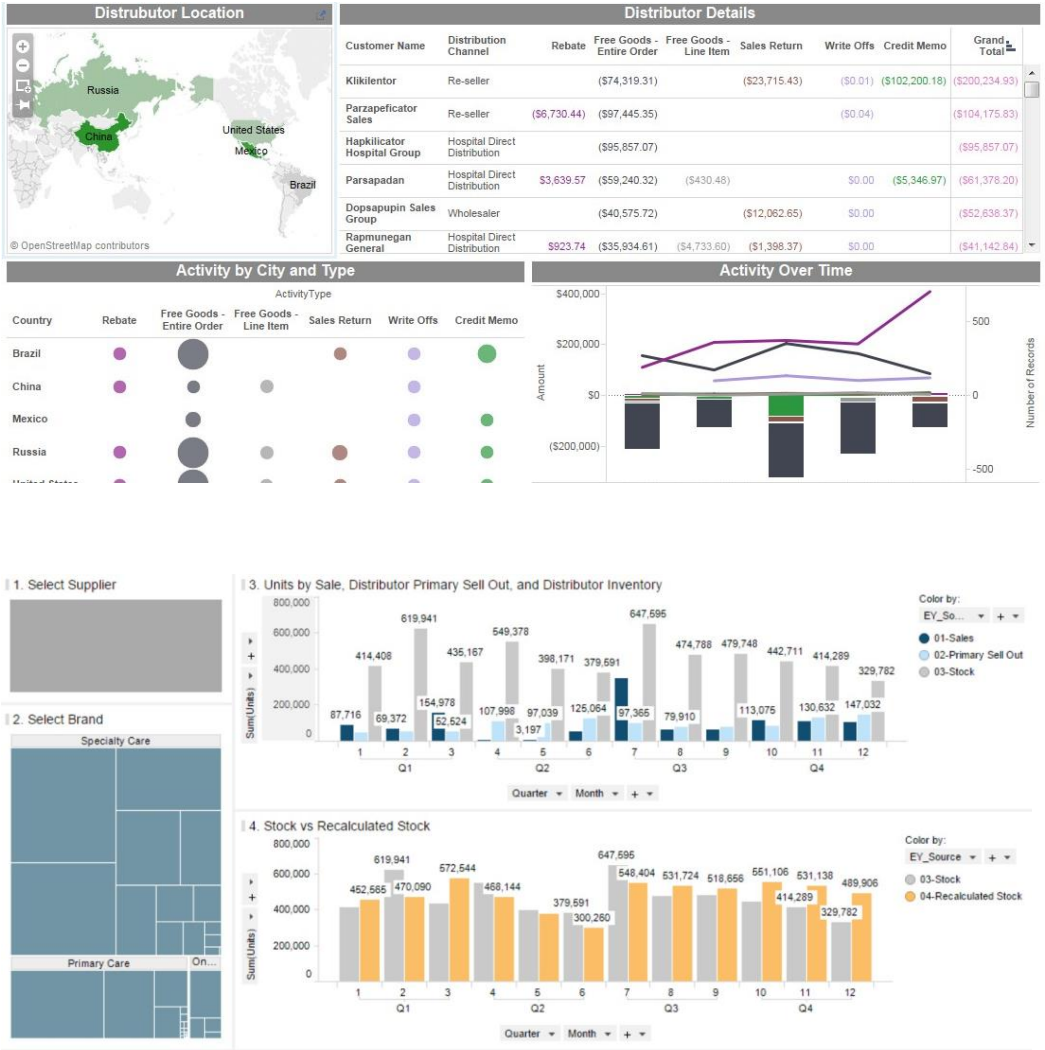


Phase 3: Analytics Design

- Select analytics matched to risks identified during planning
  - Be mindful of limitations with data and processes
  - Understand impact on KPIs and how to find the right mix of breadth across risks and depth into individual risks
- Consider cost/benefit of advanced analytics (AI, machine learning, text analytics, etc…)
- Design flexibility into methodology for mix of alerting and exploration
- Iterative tuning
  - Tune thresholds of individual tests to reduce false positives and increase detection rate
- Scoring models
  - Scalability for new data sources added down the road
  - Cadence for updating scoring and tuning of models
- Data visualization
  - Dashboards should offer capability to quickly dissect potential issues, but should not be overly complicated or intimidating
- Typical output:
  - Analytics scripts
  - Documented iterative tuning on analytics and scoring models

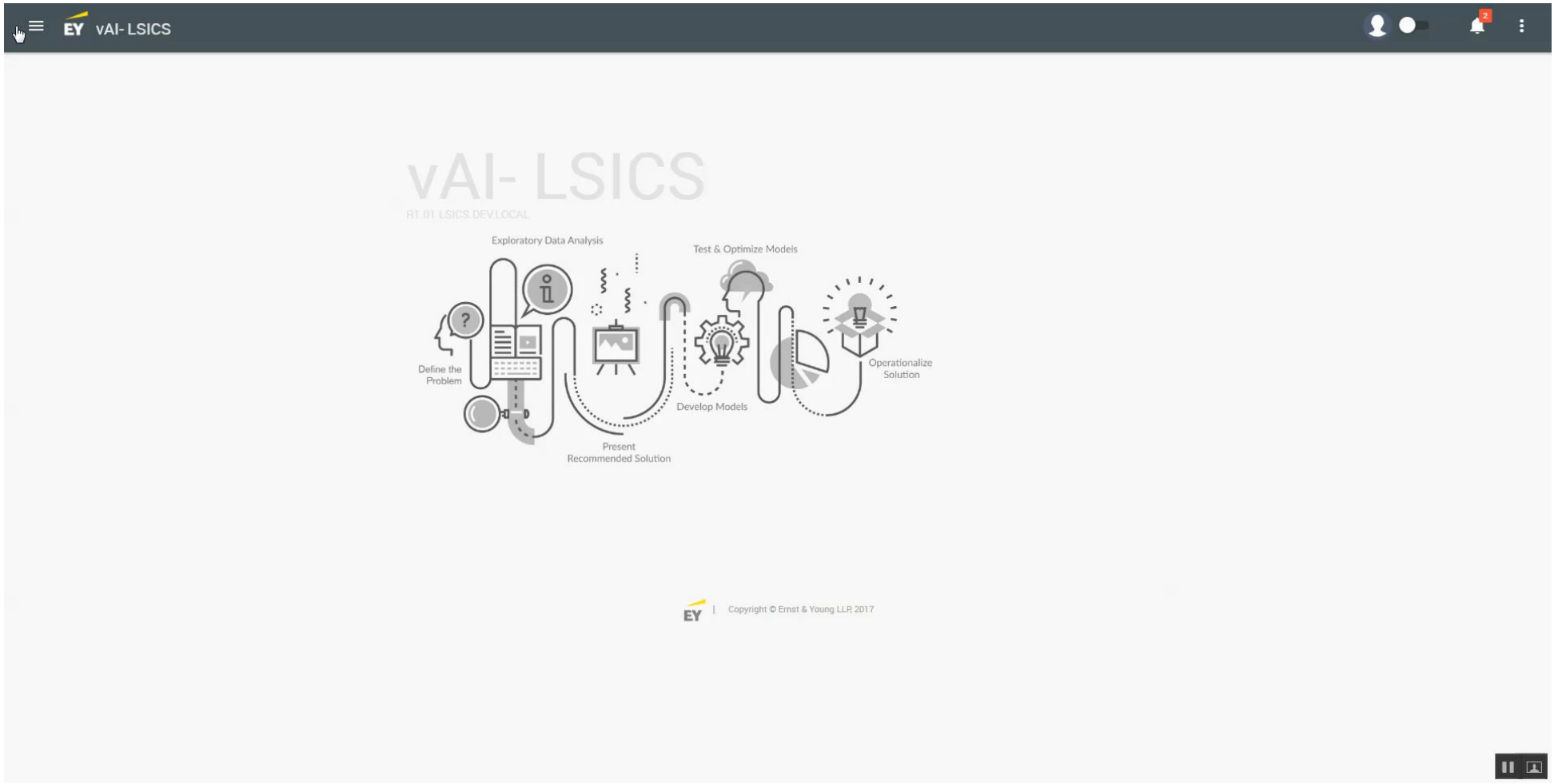
Phase 4: Reporting and Adoption

- Risk-based reporting
  - Clear justification for what is and isn't included (not the same approach / effort for all)
  - Focus on risk identification and driving improvements for the business (mitigation and remediation are critical)
  - Provide access to all stakeholders and information, as relevant (if sensitive issues are kept confidential, the program can´t adapt to monitor for them)
  - Be able to articulate impact or benefit (the 'so what')
- Review workflow which drives consistency but also allows for exploration of risks
  - Include an escalation plan
- Management reports
  - Higher level summarizations for board, audit committee, etc…
- Adoption plan
  - Training and continued support
  - Transparent metrics around adoption



Case study: Compliance Monitoring

Bringing it all together – demonstration



Thank You!

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