



# Automating Compliance Monitoring of Patient Programs in Light of Recent Government Scrutiny – Focus on Patient Data

June 19, 2019



# Disclaimer

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The views expressed and ideas presented in this session are those of the speakers and are not necessarily shared by the presenters' employers.

Any examples provided are hypotheticals and should not be attributed to any individual company.



# Introductions

SPEAKERS

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# Agenda

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- ❑ Patient Services Compliance Landscape
- ❑ Patient Services Monitoring – Data Analysis
- ❑ Potential Use Cases / Scenarios

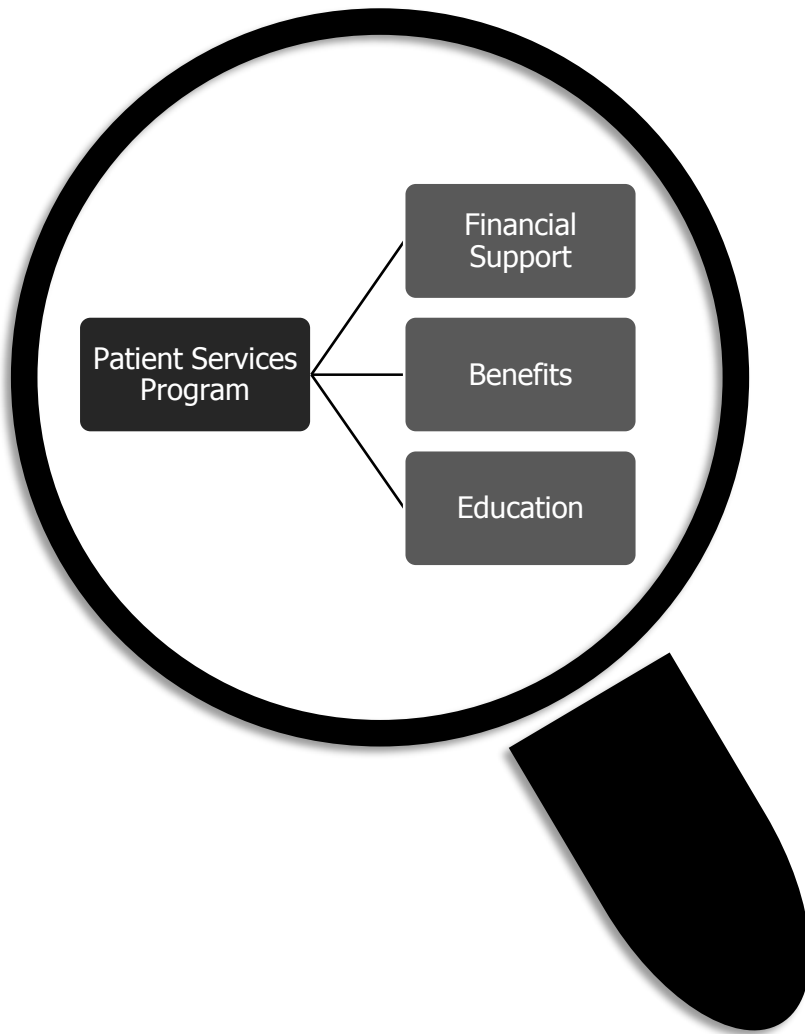


# Patient Services Compliance Landscape



# Industry Landscape

## INCREASED SCRUTINY OF PATIENT SERVICES PROGRAMS



Pharmaceutical companies have created patient services programs to aid patients in the use of their products by providing support and reimbursement services.

Pharmaceutical and biopharmaceutical manufacturers have begun receiving more attention, legal scrutiny and activity from government and other entities regarding various components of their patient support services programs.

Due to the changing landscape in the healthcare reform act as well as the increased number of specialty pharmaceuticals, this new attention and focus on compliance is becoming an increasing risk that companies are beginning to address.

# Compliance Landscape

## RECENT INVESTIGATIONS

If healthcare companies do not manage their service programs, it can increase a company's risk in various areas for litigation and investigations. Below are recent investigations filed by the DOJ/SEC for 2019:



Jazz Pharmaceuticals Sets Aside \$57 Million to Settle DOJ Probe over Charity Investigations



Actelion Pharmaceuticals Drug Maker Pays \$360 Million to Settle Investigation Into Charity Kickbacks

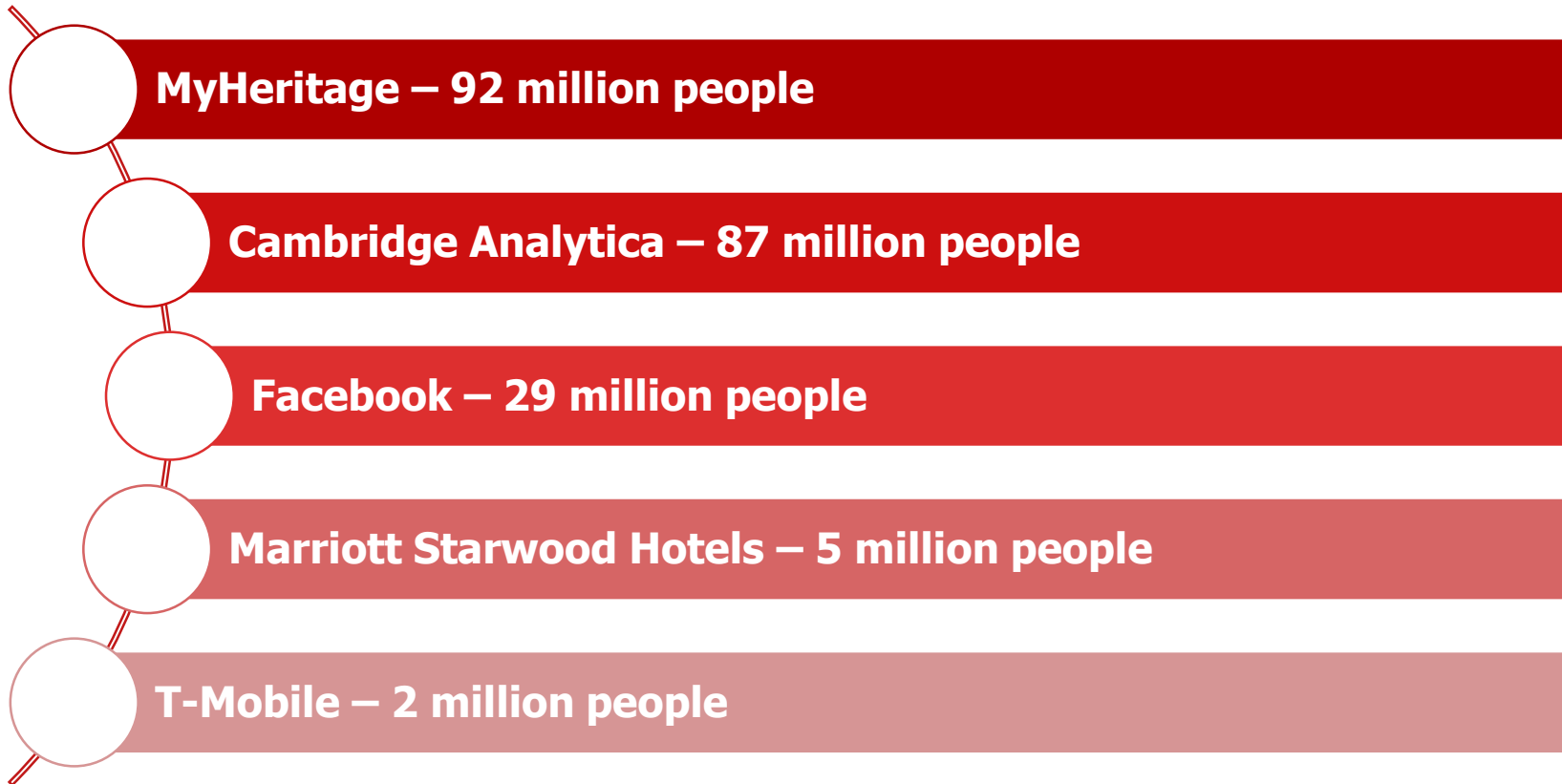


Astellas Pharma US and Amgen Inc. Agree to Pay a Total of Nearly \$125 Million to Resolve Allegations that they Paid Kickbacks Through Co-Pay Assistance Foundations

# Industry Landscape

## DATA BREACHES

Various government investigations have caused companies to examine aspects of their data service programs for compliance and risk mitigation. Listed below are a few of the largest data breaches of 2018 and the number of people affected:





# Compliance Investigation

FAILURE TO PROTECT PATIENT DATA

In **June 2019**, Quest Diagnostics, one of the nations largest providers of clinical laboratory testing services, left the personal records of **12 million** customers exposed to an unknown party, by way of a third-party data breach.

The third-party data breach struck American Medical Collection Agency (**AMCA**) of New York, a billing collections vendor that provides services to Quest.

Hackers gained illicit access to:

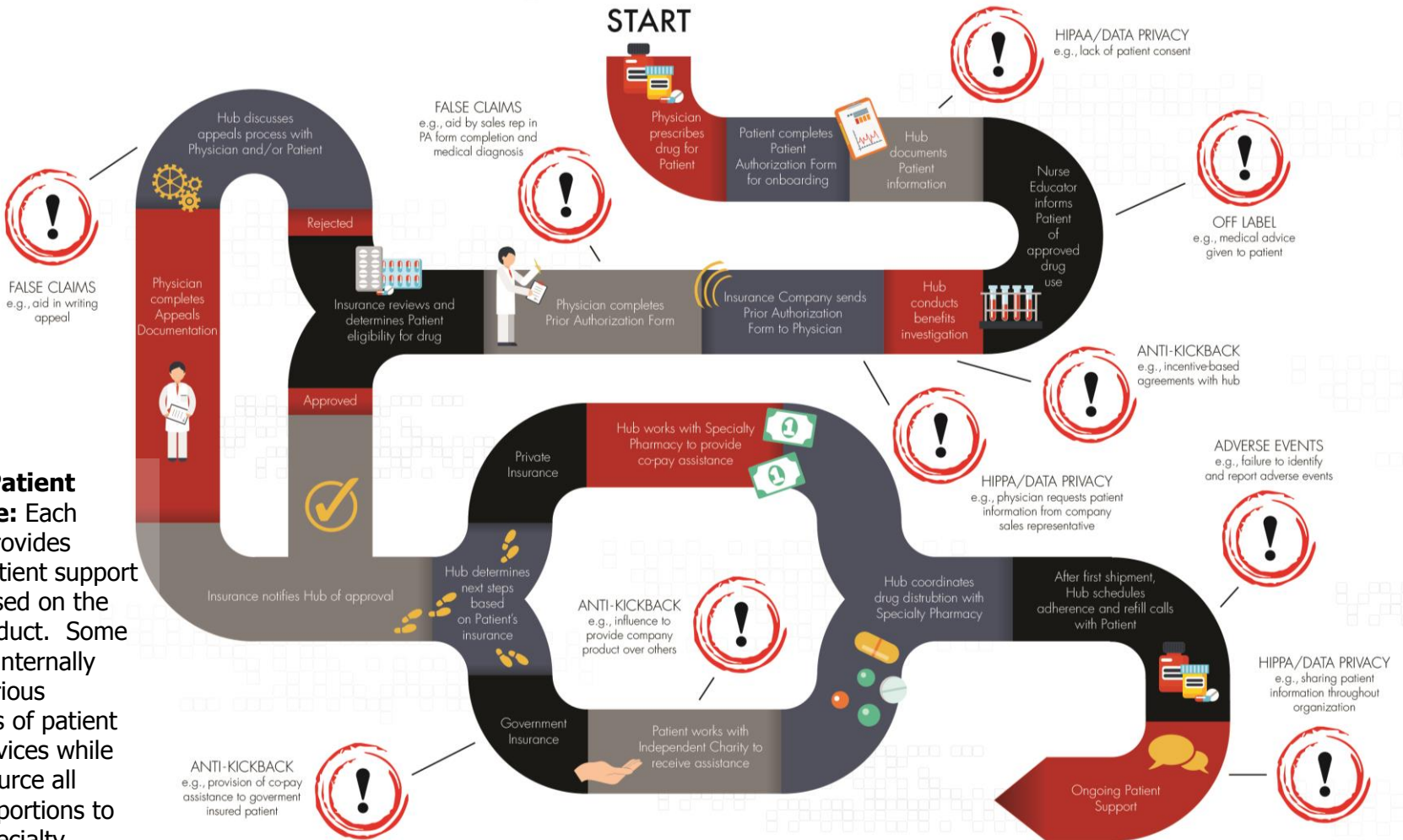
- 1) Personal information such as SSNs for identity fraud
- 2) Information about medical conditions
- 3) Financial account information



Questions raised: Why did a collections agency have access to this information in the first place?

# Potential Risk Areas

## ALONG THE PATIENT JOURNEY – EXAMPLE



**Example Patient Experience:** Each company provides different patient support services based on the specific product. Some companies internally manage various components of patient support services while other outsource all services or portions to HUBs or Specialty Pharmacies.

# Patient Services Monitoring – Automation



# Compliance Monitoring: Patient Services

MITIGATING RISK WHILE SUPPORTING EXECUTION

Increasing scrutiny of the relationship between industry and patients highlight the importance of ensuring patient service programs are not only compliant with existing regulations but also mitigating any perceived risks. The following are examples of compliance initiatives that support patient service activities:



Establish compliance controls to mitigate risk through processes and documentation of activities



Institute field monitoring: in-person and digital



Implement firewalls between sales activities and case management



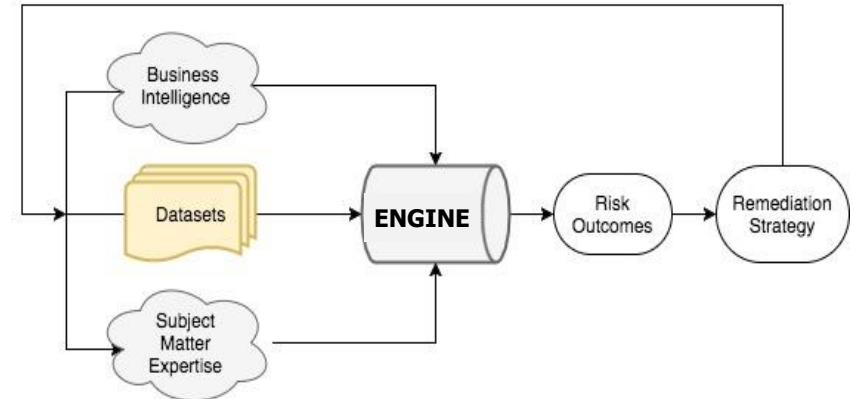
Create advanced compliance programs utilizing analytics and automated digital audits

# Compliance Monitoring: Patient Services

## ARCHITECTURE & METHODOLOGY

The implementation of an analytics engine can produce real-time results when monitoring your patient services program.

Discovered outcomes are addressed and identified best practices identified will be applied to business intelligence for future activities.



### IDENTIFY & PREPARE DATA SETS

- Gather relevant data
- Normalize, aggregate and bridge data to obtain insights from full range of information
- Identify key measures to utilize in analysis

### DATA ANALYSIS

- Establish comparative criteria and measures for analysis
- Develop algorithms to evaluate data
- Score risk areas and organize risks by priority
- Anticipate future risk from historical contexts and trends

### CREATE VISUALIZATIONS

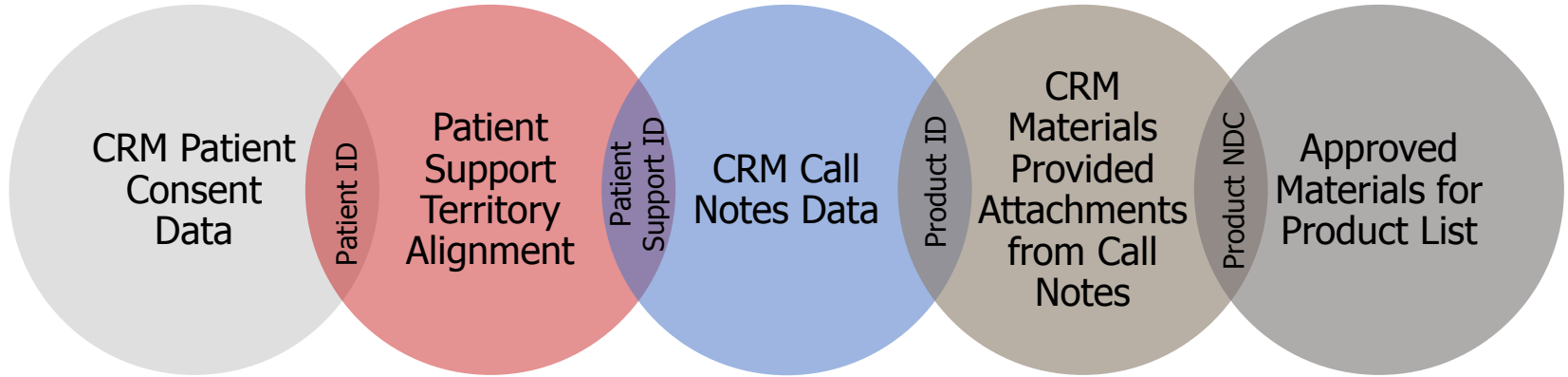
- Develop supporting visualizations to provide valuable insights
- Develop full view to understand scale of identified risks

### REMEDIATION

- Develop strategic plan to mitigate identified and potential risks
- Determine gaps, weigh key attributes and identify areas of improvement to prevent future occurrences

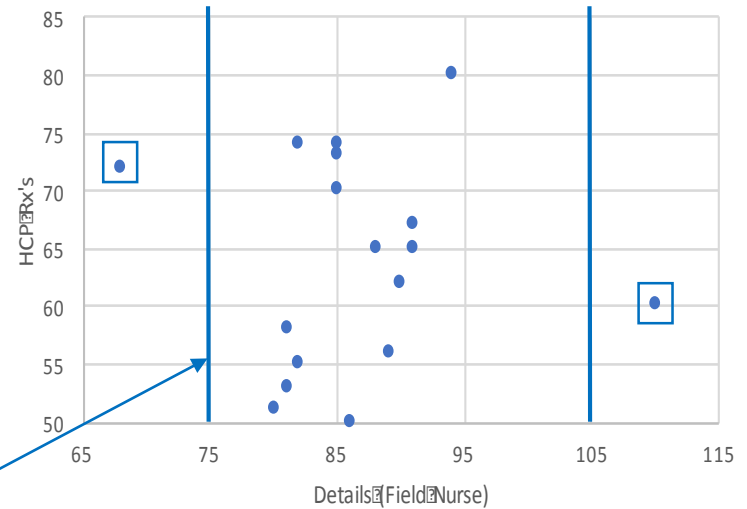
# Compliance Monitoring: Patient Services

IDENTIFY & PREPARE DATASETS



The key to gathering insightful information is to prepare accurate data. By gathering relevant datasets and normalizing the information, a biopharma can optimize analytic capabilities.

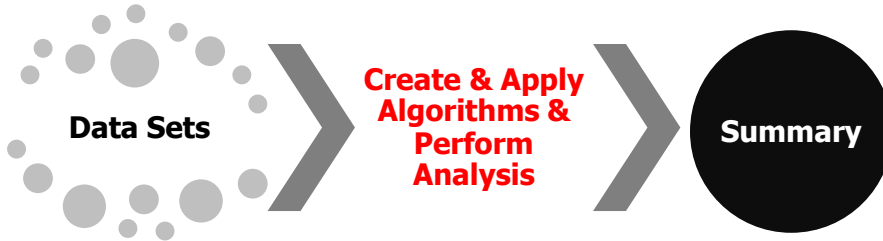
The key to this model is to bridge datasets to extract the full range of intelligence for patient services and compliance teams to evaluate.



Normalize datasets to define risk constraints

# Compliance Monitoring: Patient Services

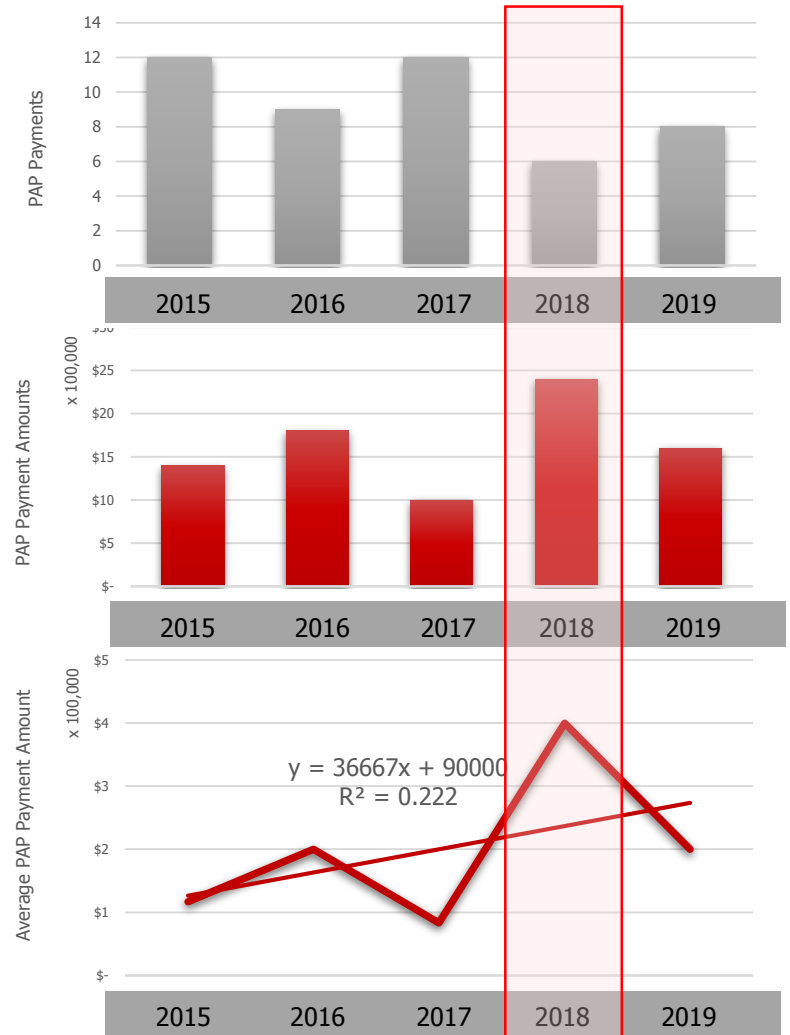
## DATA ANALYSIS



Next step is to establish risk criteria and measures to analyze the datasets against. Based on these measures, algorithms can be developed to dissect the data and provide the required compliance monitoring metrics. Algorithms can be run as often as the data is updated to provide up-to-date, real-time results.

A data engine will also weigh these attributes with historical context to measure how likely future violations will occur. Key stakeholders can then decide next best actions and allocate the proper resources to minimize those prospects.

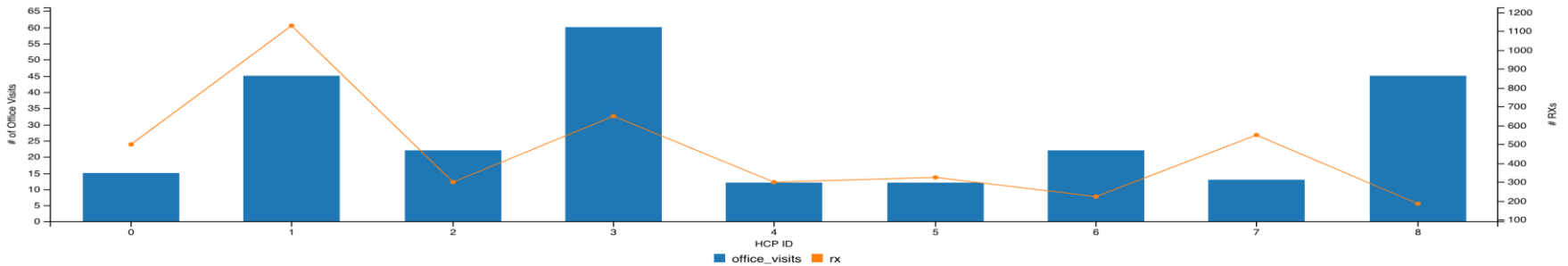
The goal is to continuously refine the engine to consistently provide value to each company's Compliance program.



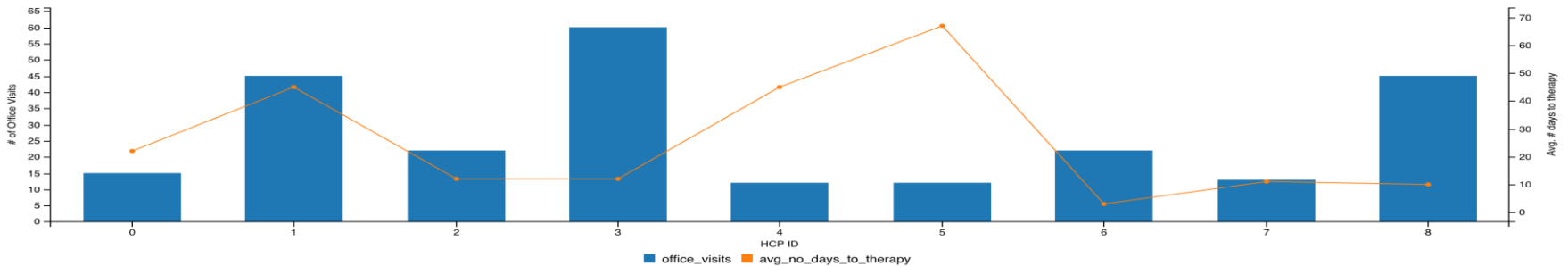
# Compliance Monitoring: Patient Services

## VISUALIZATIONS

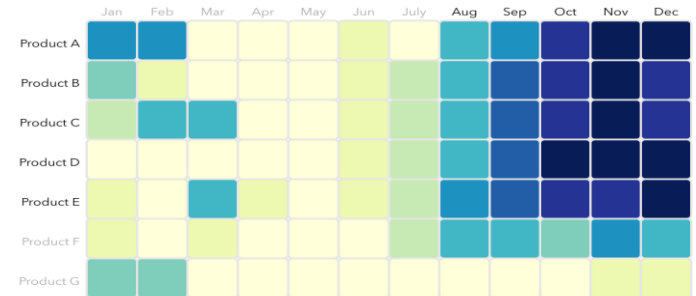
Customer Touchpoints (RX)



Customer Touchpoints (Avg. Number Days to Therapy)



Aggregated Patient Interaction Counts



Visual dashboards will provide the supporting details to help our clients understand where areas of risk are occurring and the story behind these areas. Helio strives to give our clients the full view of the landscape before assessing next steps.



# Compliance Monitoring: Patient Services

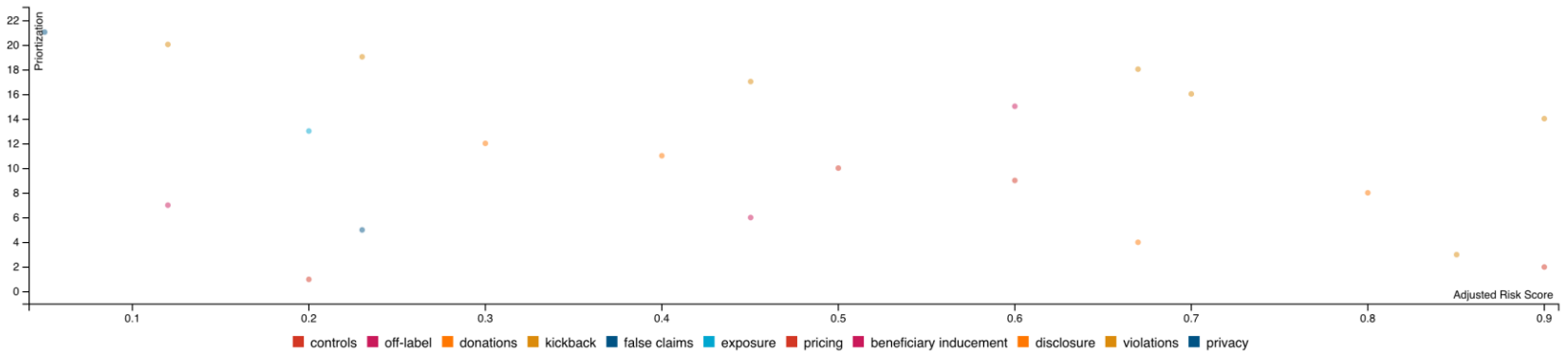
## LIVE MONITORING AND ADDITIONAL AUDIT FUNCTIONALITY

A Patient Services team or its delegates (vendors) should create and document live monitoring or other assessments and audits of its various groups and employees.

This functionality allows all qualitative and quantitative analyses to be completed and compiled in the same tool. Additionally, an engine will summarize the data and create visualizations of the outcomes of these audits / monitoring activities for additional usage or presentations.

The inputs of these audits / monitors or reviews can be updated and changed at any time by managers of the tool. Examples of usage of these can be patient advocate speaker program monitors, patient support services team ride-a-longs, hub audits, etc.

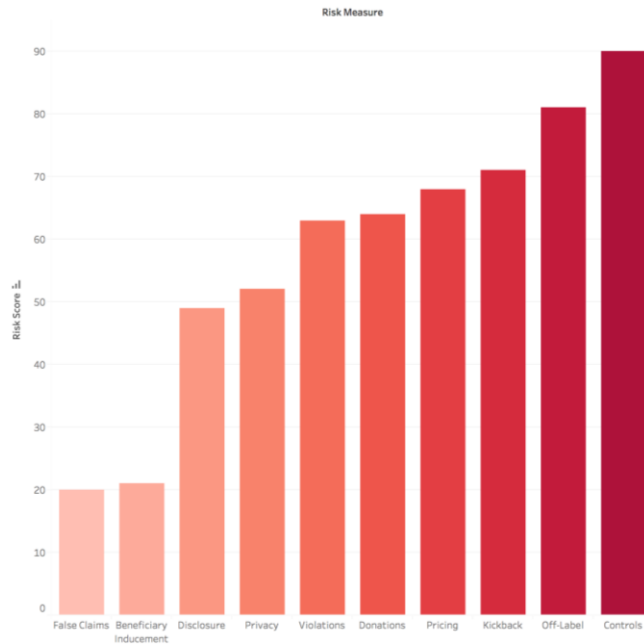
- FALSE CLAIMS
- DISCLOSURE
- EXPOSURE
- DONATIONS
- CONTROLS
- PRICING
- VIOLATIONS
- BENEFICIARY INDUCEMENT
- OFF-LABEL
- KICKBACK
- PRIVACY
- RESET



Measure	Measure Detail	Measure Score	Monitoring Switch
Did any Patient Engagement Team members, HUBs, Specialty Pharmacies complete / falsify any information for patient enrollment, patient consent, prior authorization, appeals, etc.?		0.23	Turn Monitoring Off

# Compliance Monitoring: Patient Services

## REMEDIATION



controls

Measure	Measure Detail	Measure Score
Does each foundation determine a patient's qualification for financial assistance based solely on his or her financial need?		0.12
Size and nature of Patient Assistance Programs (in terms of foundations, patients, and therapeutic areas)		0.2
Was patient specific information shared between Patient Engagement Team members, HUBs or Specialty Pharmacies?		0.9
Were there any deviations to Standard Operating Procedures by Patient Engagement Team members?		0.23
Were there any violations to HIPAA Guidances?		0.12
Are controls in place at your organization to ensure that data isn't being transmitted back to you?		0.9

Based on the results of the data analysis, a biopharma should look for summaries of identified risk areas and group them by category. Risk summary will indicate issues with high priority and suggest actionable recommendations for remediating identified risks as next steps.

The key is to develop strategic plans to mitigate risks and to prevent them from happening in the future.

# Patient Use Cases / Scenarios



# Compliance Monitoring: Patient Services

## POTENTIAL COMPONENTS & DATA SOURCES

The following are some high level areas that has various components that can be monitored to address various risks. Additionally, from a Patient Services standpoint, this may include monitory services provided by HUB providers or internal services, based upon who is conducting the activity.

Patient Consent

Prior Authorizations / Appeals

Patient & HCP Interactions

Patient Adherence

Patient Communication

Patient Data Usage & Sharing

Patient Materials

Patient Assistance Programs (PAPs)

# Use Cases / Scenarios

## PATIENT DATA



### Questions to Answer

Are there any patient data sets that are currently out of compliance and increases your company's risk profile?

### Example Metrics

- Comparison of patients enrolled in patient services program to list of patients agreeing to consent
- Potential off-label indications were mentioned to a patient or HCP
- Comparison of patient insurance information against patients currently enrolled in PAPs



- Patient Support Services Territory Information
- CRM / HUB / SP Call Notes
- HCP information (CRM) including patient scripts

- Effectiveness and Optimization of Patient Services activities and interactions with patients in a compliant manner
- Potential ANTI-KICKBACK issues

### Key Data Sources

### Potential Insights

# Contact Us

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<https://www.surveymonkey.com/r/Helio2019PSSurvey>

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