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# **Mini Summit 11** **Best Practice in HCP / HCO Management to Reduce Compliance Risk and Enhance Efficiency**

*18<sup>th</sup> ASIA PACIFIC PHARMACEUTICAL  
AND MEDICAL DEVICE ETHICS AND  
COMPLIANCE CONGRESS*

**September 10 - 12, 2018**  
**Shangri-La Hotel**  
**Singapore**

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# Best Practice in HCP / HCO Management to Reduce Compliance Risk and Enhance Efficiency



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**Speaker Bio**



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**Speaker Bio**



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Managing Director, Polaris Asia-Pacific; Former General Manager, Eli Lilly Asia Inc., Hong Kong (Moderator)

**Speaker Bio**

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  - Case sharing: Olympus' harmonized approach through Technology for HCP/HCO management
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**What is the Global Trend for HCP/HCO management?**

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03

# What are the key challenges and compliance risks Associated with HCP / HCO Engagements?

- Kickbacks or bribery through Transfer of Value to HCP
  - › spend on entertainment;
  - › unwarranted payments for speaking engagements;
  - › improper sponsorship;
- Compensation does not reflect Fair Market Value
- Compensation to HCP without a contract in place
- The event did not happen / no documentation to prove the event is actually taking place
- Improper Transfer of Value through Third Parties:
  - › Distributors
  - › Travel agency / Meeting organization, etc.
- Lacking of clear “Academic needs assessment” methodology with local authority’s common recognition which could justify the engagement with HCP/HCOs
- Public perception of undue influence on HCPs, “linking” of HCP/HCO engagement with prescription and company’s revenue
- Whether sales target should be Med. Rep’s KPI whose daily work is interacting with HCP/HCOs.
- When the pharm industry BE trend goes to more and more transparent, it might go to an extreme direction to disclosure everything when engaging HCP/HCO, which is fair comparing with other industry
- Painstaking processes to check the compliance rule for cross border invitation, and sometime may end-up with wrong/incorrect application of the rule
- Not easy to know recommended / proper HCP/HCO with proper conditions for invitation
- Complicated/troublesome data management for due regulatory reporting etc.



**How company manage the huge number of HCPs / HCOs and events effectively?  
And stay away of Anti-Bribery and Anti-Corruption Risks**

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How company address these challenges?



## <Ferring's Case>

Implement the Compliance Technology Solution

=> Global / Cross Border IT tool / Polaris

### Before

- Painsstaking compliance rule confirmation **Not Effective**
  - by e-mail/phone communications (host ⇔ home)
  - host to refer/apply the information, but, usually not having final check by home **Risk**
- Complicated / troublesome data management for due regulatory reporting for various countries **Not Effective**  
etc.



### After

- Systematic processes for compliance check, etc. through the IT tool system
  - review and approval workflow (activity initiation, HCP nomination, contracting, activity closeout, etc.)**Reduce Compliance Risks** **Effective**
- Enable to capture and aggregate spend data for transparency reporting (at reporting home countries)  
**Effective**

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# HARMONIZED GLOBAL APPROACH & CASE STUDY

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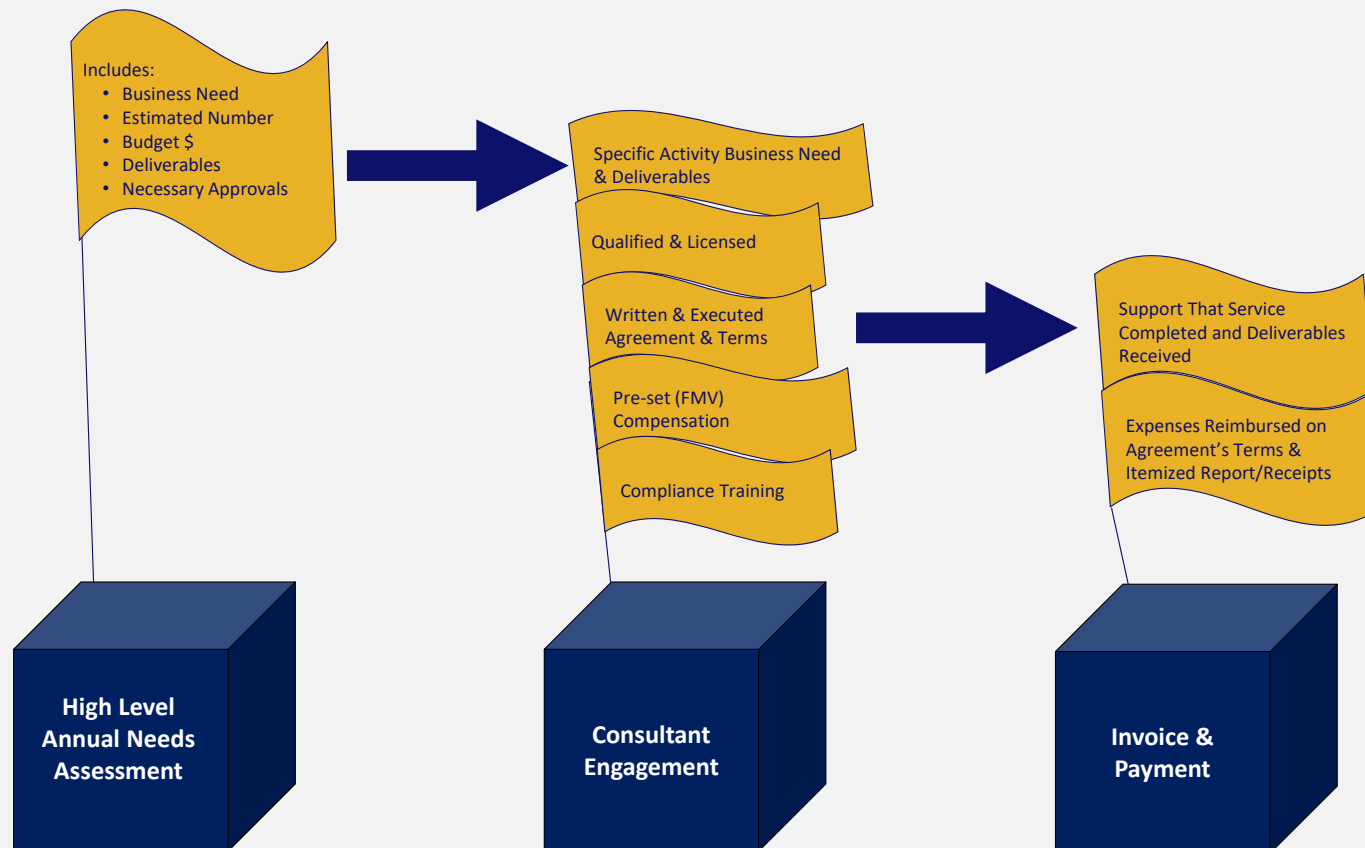
## Global & Local Alignment of Company HCP Consulting Arrangement Process

- Seeking to leverage global resources to adapt the Compliance Program for local use and needs
- While all processes are not the same, the general processes are in harmony





# HCP Consulting Arrangements Policy & Process – Key Objectives



## Case Study

The poster for EUS2018 features a blue background with white and yellow text. At the top left, 'EUS2018' is written in large, bold letters, with 'EUS' in white and '2018' in yellow. To the right is a circular logo with '21st' and 'EUS2018' inside. Below the title, the text '21st International Symposium on Endoscopic Ultrasonography' is in small white font, followed by 'December 1 - 2, 2018 • Bangkok, Thailand' and 'Hosted by TAGE & Olympus'. The section 'International Board Members' is highlighted in yellow. It lists roles and names in two columns: Chairperson (Lawrence Khek-Yu Ho, Singapore), Co-chairperson (Thawee Ratanachuek, Thailand), Chair Mentor (Bertrand Napoleon, France), Secretary General (Rungsun Rerknimitr, Thailand), Advisory Board (Paul Fockens, The Netherlands), Robert Hawes (USA), Thomas Rösch (Germany), Kenjiro Yasuda (Japan), and Secretariat (Isseki Kawahara, Olympus).

**EUS2018** 

21<sup>st</sup> International Symposium on Endoscopic Ultrasonography  
December 1 - 2, 2018 • Bangkok, Thailand  
Hosted by TAGE & Olympus

**International Board Members**

<b>Chairperson</b> <b>Lawrence Khek-Yu Ho</b> (Singapore)	<b>Advisory Board</b> <b>Paul Fockens</b> (The Netherlands)
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<b>Secretary General</b> <b>Rungsun Rerknimitr</b> (Thailand)	<b>Kenjiro Yasuda</b> (Japan)
	<b>Secretariat</b> <b>Isseki Kawahara</b> (Olympus)

- Olympus organized international event
- Engagement of HCPs from throughout the world
- HCP Consulting Arrangement Processes, Written Standards and Training Harmonized throughout Olympus Group
- Global Compliance function coordinating to Monitor the event to test controls working as designed

Compliance Monitoring is...



*Active listening and observation of field activities in their natural state in order assess whether practices of Company Representatives are consistent with Compliance policies and procedures and to identify opportunities to strengthen business operational controls and the Compliance Program.*

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## Discussion Points

- What kind of Global trend that you are seeing regarding managing HCP / HCO to reduce compliance risks?
- How you see the evolution of HCP / HCO management in your company? What kind of changes your company is going to do in the near future?
- Technology: How technology can help? What value it can bring to compliance and to the company?
- Data analytic: How data analytic can support compliance? And what value it can bring to the business?

# Global Compliance Technology Platform: Bring in Values

## Situation

- Increasing **compliance obligations** in primary revenue markets, represented 60-70% of company revenues
- Lack of a **single tracking process** across HCP financial engagements
- HCP engagement systems over 19 countries, **no centralized or standardized** data systems in place, systems are **disconnected**. 12 countries had no IT systems for HCP review / approval.
- **Time consuming to generate compliance report**, data sitting in different systems and some were manually captured
- **High IT costs / maintenance cost** due to system complexity and lack of manageability



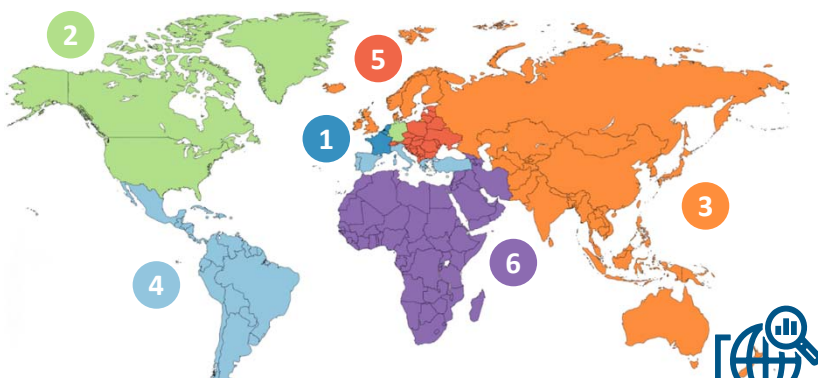
## Objective

- **To implement a single global solution for standardizing and managing the HCP/HCO engagement process** for 35,000+ planned users in different businesses and regions
- **Established a long term solutions** to address the growing reporting regulations
- Develop an ability to **monitor and audit** HCP/O transactions effectively
- **Retire 20+ legacy systems**



## Solution

- Deploy a global interaction portal to **manage marketing and medical activities, cross boarder activities, sponsorships, grants and donations, investigator initiated studies**
- **Aggregate data** for various reporting entities
- **Improved data integrity** with one source of validated master records
- **Interface** with existing company systems: CRM/Veeva, T&E/ SAP, third party data.
- One portal provided **single sign-on** access to various systems



Ongoing Roll-out Phases

## Outcomes and ROI

- **Automated end-to-end process** from approval to transparency and **reduced risk exposure** globally
- Tracked, approved, and reported all HCP and HCO value transfers with **built in control and validation point**
- Able to generate routine **reports to support ongoing monitoring and auditing**
- Solutions now increase both business and IT efficiencies, also providing **simplicity, standardization, compliance and sustainability**
- Successful project completion will result in **retiring 20+ legacy systems with 12+ years history, and integration with 10+ current systems**
- The teams that have been using the system report **greater efficiency and accuracy**, allowing them to devote time to other critical tasks



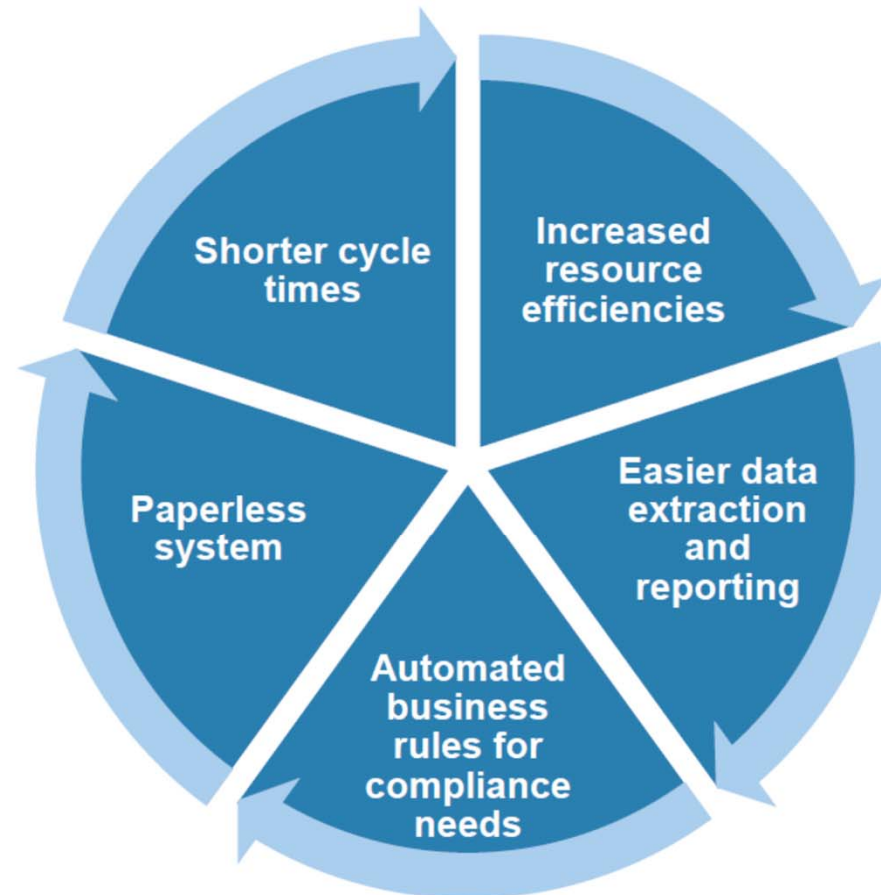
# Technology Brings Business Benefits across all HCP/O Engagement Processes

## Reduce processing times for requests

- Shorter document creation time
- Contracting efficiencies
- Centralized HCP profile reduces nomination reviews

## Requests tracked in electronic environment

- Minimization of paper-based process elements
- Less paper used meets environmental concerns



## Reduction of manual procedures

- Automated documentation of approvals
- Interfaces will reduce double-entry
- Automation allows for more value-add activities and analysis

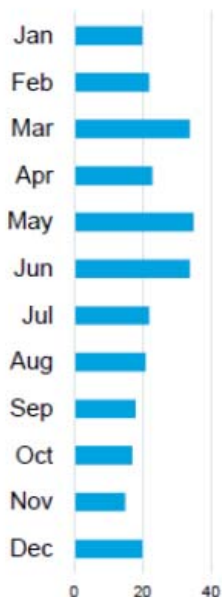
## Central data repository for reporting and auditing

- Aggregate spend data capture
- Analyze utilization of HCPs and services
- Automatic updates to dashboards

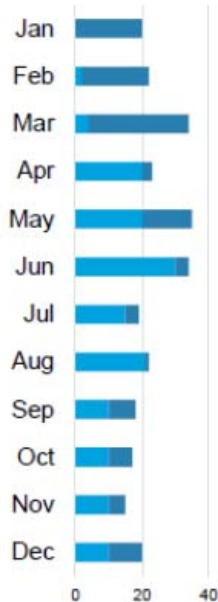


# Platform Provides KPI Reporting To Track And Improve Operational Processes

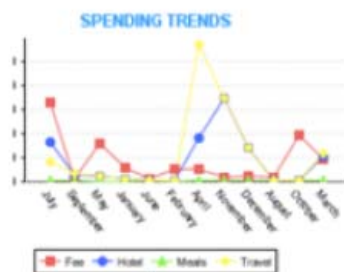
## Engagements per month



## Spend capture vs. pre-approval

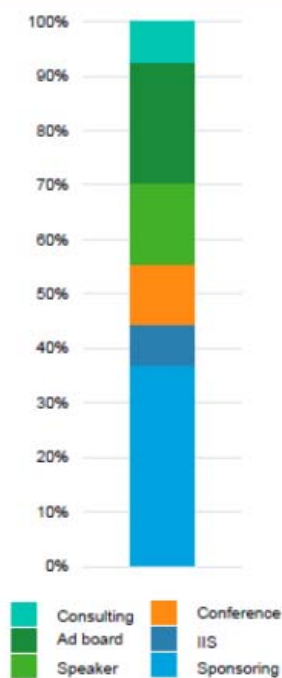


## Spending trends

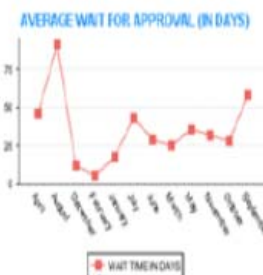


Trend per spend type

## Spend per activity type



## Average processing



Days waiting

# What Is Compliance Data Analytics?

- Definition

*Utilization of technology and data analysis techniques to identify trends and anomalies, while deriving meaningful insights into transactional based data sets*

- Data analysis techniques

- Statistical (descriptive)

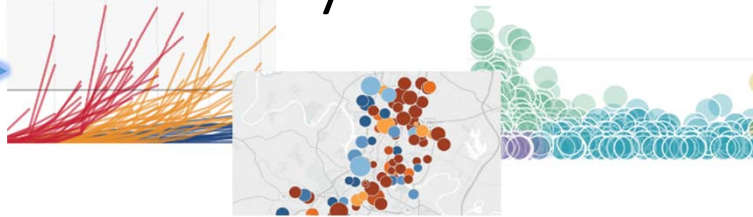
- Mean, median, standard deviation, regressions, stratification (groups)
    - Summarization of data set

- Automated (rule based logic)

- Defined rules or logic, automated through scripting, to derive subsets of data/reports that may be used for further analysis
    - Exception reporting; records or transactions that fall outside of a defined tolerance or threshold

# What Is Compliance Data Analytics?

*Visualization*

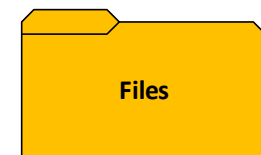
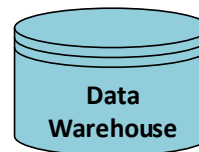


*Analysis*

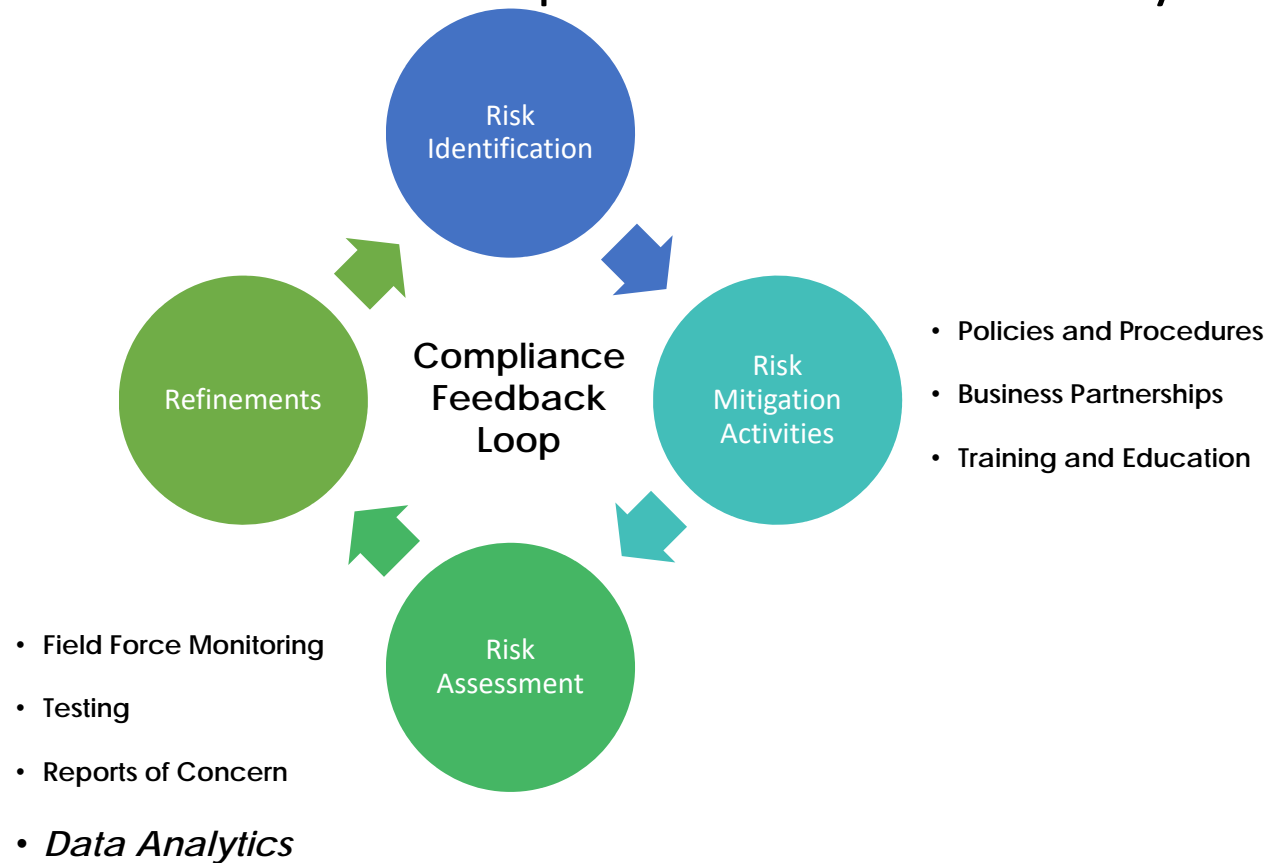


- Data normalization
- Data blending
- Exception Reporting

*Raw Data*



# What Is the Value of Compliance Data Analytics?

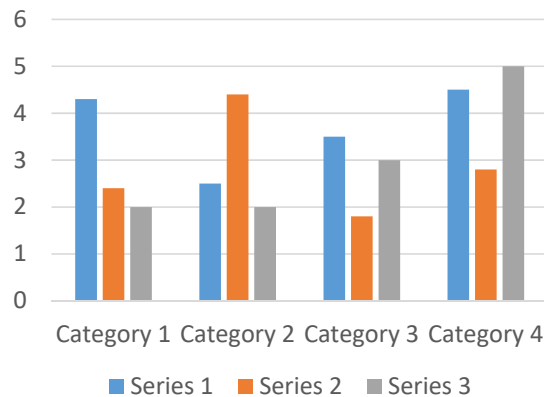


# Example of Data Visualization: Monitoring Activity KPIs

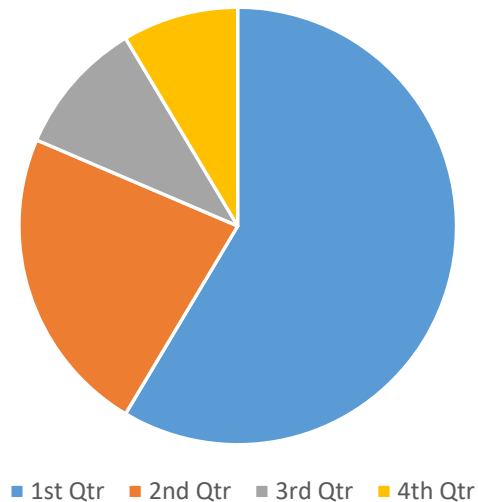
Field Force Monitoring activities include:

- Ride Alongs with Sales Representatives
- Advisory Boards Activities
- Conference/ Sponsorships Activities
- Speaker Programs
- Professional Education Courses
- Grant Supported Workshops

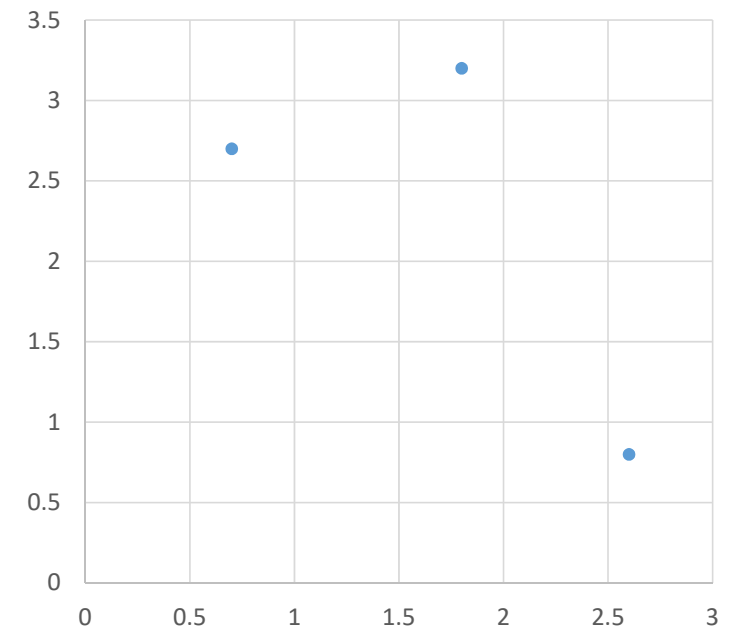
## Monitoring Activities



## Monitoring Observations



## Monitoring Anomalies



# Comprehensive Framework to Successfully Manage All HCP/Os Engagement / Activities



## End to End Process Automation

- Automate business rules for compliance needs
- Actual implementation are align with SOPs
- Consistent practice across different business unit / countries / regions
- Manage huge amount of HCP/O engagement and activities
- Capture all transfer of value data in the same system



## Build in Control and Validation point

- **Approval needed**
  - Events and payments can not occur without proper approvals and sign offs
  - Needs assessment, HCP selection criteria, FMV, contracting, validation of services and payment
- **Build in caps and thresholds**
  - Annual operational plan & budget plan, with number of events cap / budget cap
  - FMV rate table, with exception processing
- **Upload documentation**
  - Signed contract
  - Notification from HCP institution (if needed)
  - Receipts, attendance list, CME form, meeting minutes, photos, etc
  - Support dispute process



## Data Analytic to support On-going Monitoring

- Analysis based on Key Risk Indicators
- Routine report generation to identify outliers
- Spot risk areas by looking at the trend
- Report on operational and financial metrics to support business decision
- Any piece of data entered in the system can be reported and analyzed for ad hoc report