Advanced Strategies in Auditing and Monitoring

Wednesday, November 7, 2018

Agenda

8:00 – 8:20	Opening remarks and introductions of panel members
8:20 – 9:00	Understanding of current programs through deep dive risk assessment methodology and current approaches to auditing/monitoring
9:00 – 9:15	*Break*
9:15 – 10:00	Review of recent Corporate Integrity Agreements • Emerging areas (patient assistance programs, funding to foundations) • Considerations for monitoring – changes in approach, what's effective?
10:00 – 10:15	*Break*
10:15 – 11:00	Life post-CIA or for those companies who have not been under CIA (reallocating focus and resources)
11:00 – 11:15	*Break*
11:15 – 11:45	Questions from audience, networking and benchmarking with peers
11:45 – 12:00	Closing remarks

Introductions

Panel

James Accumanno
Director, Risk, Monitoring and Auditing, Novo Nordisk; Former Associate Counsel, Bayer, Philadelphia, PA

Amy Pawloski
Compliance Officer, Operations, Endo Pharmaceuticals, Malvern, PA

Yogesh Bahl
Managing Director, AlixPartners, New York, NY

Kathryn “Katie” E. Winson
Senior Manager, US HCC Monitoring, Celgene Corporation, Summit, NJ

Nicole Chandonnet
Associate, Covington & Burling, Washington, DC

Emily Huebener
(Moderator)
Forensic and Integrity Services, EY, Chicago, IL

Understanding of current programs:

- Risk assessment methodology
- Approaches to auditing/monitoring

Monitoring Agenda

- Defining Objectives and Scope is Key
- Develop Approach and Socialize
- Select Pilot Areas
- Develop Data Interrogation Approach
- Transforming Data Analytics into Monitor

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Defining Objectives & Scope is Key

Objectives

- ✓ Enhance compliance monitoring activities in specific pilot program areas
- ✓ Leverage current data repositories to capture critical information and identify anomalies and correlations
- ✓ Manage risks proactively by developing the ability to identify potential issues before they occur
- ✓ Leverage results to port to other program areas, as applicable

In Scope

- ✓ Entities
- ✓ Systems, data, processes and controls for pilot program areas

Out of Scope

- ✓ Evaluation of systems, controls, processes and organizational elements

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Create and Define Your Approach

	Phase 1: Plan & Scope Risk Areas	Phase 2: Translate Risks	Phase 3: Evaluate Data Availability	Phase 4: Pilot Analytics	Phase 5: Finalize
Objective	Confirm key risk areas to be addressed through the data analytics program and review pilot activities for data analytics	Translate risks within Company's risk assessment associated with the selected programs' activities into potential inquires for which analytics may reduce risk exposure	Determine availability of Company's data to analyze each prioritized data interrogation question	Develop pilot analytics on available data to determine effectiveness for responding to inquires	Finalize analytics, review outcomes, prepare reference document
Activities	• Execute a high level review of Company's existing risk assessment and provide additional industry insights • Confirm two programs for piloting a data analytics program (e.g., speaker programs, IISR) • Conduct project planning meeting	• Analyze external sources (e.g., CIA's requirements) • Review internal sources (e.g., "business risk input engine", call center, CAPA findings) • Prepare a list of data interrogation questions that would be relevant from a compliance perspective • For the population of questions evaluate Company's ability to take action and review target questions with Legal • Prioritize the list of data interrogation questions based on discussions with Company	• Develop business rules that will be required for the data request • Identify all data fields and sources needed to evaluate each question • Evaluate the availability of data and data sources for use in pilot (via qualitative review with IT) • Develop a data request from source systems • Identify and agree upon a data transfer protocol for transfers of data • Collaborate with Company's IT contact to facilitate the data export for analysis	• Develop the analytical tests to answer the data interrogation questions • Perform data quality and integrity tests to evaluate completeness and suitability for analysis • Evaluate the output: of the analytics to understand anomalies/outliers and determine utility of analysis • Identify suggested improvements and changes to the analytics • Establish process to further evaluate outliers (e.g., monitor future trends, investigate each instance, etc.)	• Review outcomes of analysis and identify appropriate next steps (e.g., start, stop, continue) • Recommend key areas of focus and ongoing data analytics for auditing and monitoring compliance activities • Prepare reference document summarizing objectives, process, analytics, and recommendations

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Pilot Program Selection Process

Using core team input, the overall list of areas of focus can be reduced to a “Short List”

Overall List

- Speaker Programs
- HCPs as Consultants/ Advisory Board
- Investigator Initiated Sponsored Research (IISR)
- Field Interactions with HCPs
- Grants
- Charitable contributions
- Social Media
- Government price reporting
- Anti- Bribery

Core Team Input

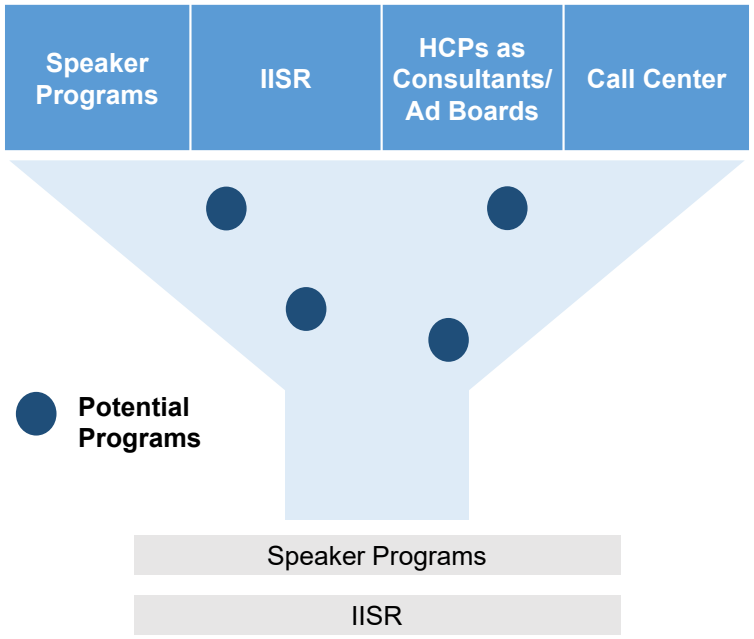
Short List

- Speaker Programs
- IISR
- HCPs as Consultants / Advisory Boards
- Call Center

Pilot Program Selection Process (continued)

To select two pilot programs, a set of logical criteria can be applied:

Short List



Criteria

Risk Level:

- ✓ ***Area has higher risk exposure***
- ✓ ***Area has residual risk despite existing system controls***

Value to Company:

- ✓ ***Frequency of transactions***
- ✓ ***Value of transactions (associated spend)***

Feasibility:

- ✓ ***Existing data supports analytics (e.g., quality of data, amount of data, volume of transactions)***

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Data Interrogation: Take a Step by Step Approach

Step 1. Define business process categories	Translate pilot program components into high level process steps.
Step 2. Identify risk criteria	Apply a set of risk criteria to identified process steps to enable the identification of granular risks associated with the relevant process step.
Step 3. Identify associated risks	Identify business risks that are specific to the process steps as identified in step 1 above and risk criteria as identified in step 2 above.
Step 4. Identify available controls	Confirm if controls are present for the above business risks. *Note: This process is not to document all manual and automated controls, but rather to give a sense of the potential residual risk after existing controls are considered.*
Step 5. Create potential questions for analytics	Develop a list of questions for which analytics may reduce risk exposure.

Data Interrogation Step 1: Define Business Process Categories

Create process categories to facilitate risk identification

1. Select speaker	2. Engage speaker	3. Develop content	4. Approve SP	5. Execute SP	6. Closeout SP	7. Manage speaker utilization
1	2	3	4	5	6	7	8	9	10

Process #	Key components of the process
1	Speaker bureau strategy approval
2	Speaker nomination/ selection
3	Speaker agreement/compensation
4	Speaker training activation
5	Speaker program content
6	Speaker program approval
7	Speaker program venues and meals
8	Program host responsibilities
9	Program closeout
10	Speaker utilization and management

Key components: Speaker Program process
Identified business processes

Data Interrogation Step 2: Decompose Process Steps Using Risk Criteria

The following high-level risk criteria can be used to decompose the process steps in an effort to identify a holistic set of risk areas. A brief description and an example is provided for each category. Not all criteria will be applicable to all business processes.

Risk Criteria	Description	Examples
Audience	***Who*** is the target of the process step?	• Are any of the investigators or speakers on the regulatory debarment list?
Message	***What*** is the content of the process step?	• Is the content of the summary of proposed research scientifically appropriate?
Timing	***When*** does the business process occur?	• Does budget committee signoff before the study gets approved? • Are all employees who have nominated a speaker up to date on required training at the time of nomination?
Location	***Where*** was the location of the business process?	• Is site proposed likely to result in payment to a government employee? • What is the percent of speakers travelling more than 300 miles to execute speaker programs (where 300 miles = national limit)?
Budget/ Payment Mechanism	***How*** was the amount related to the business process determined/made?	• Is there a prevalence of significant budget amendments? • Are certain speakers always being paid at the highest end of the range relative to their peers?
Alignment to Strategy	Was the business process in ***alignment*** to ***business strategy***?	• Are study justifications aligned with pre-defined study objectives?

Data Interrogation Steps 3-5 to Develop Questions for Analytics

The following example pertains to Speaker Programs and represents the results of steps 3 through 5 per the data interrogation approach, including: (1) identifying associated risks; (2) identifying available controls; & (3) Creating potential questions for analysis.. This particular example relates to the “Engage speaker” business process category analyzing the risk criteria “budget/payment.”

Risk Category	Step 3: Associated Risk	Step 4: Examples of Available Controls	Step 5: Potential Questions for Analytics
	• Negotiated payment is above Fair Market Value	• Yes – FMV tool is built into the speaker program system	• How many speaker rate changes requests were approved? • Has fee schedule or rate cards been edited for the particular speaker? Is there documentation to support the change?
Budget/ Payment	• Speaker compensation is always at top of range	• Unclear	• Are certain speakers always being paid at the highest end of the range relative to their peers? • Are speaker activation expenses reasonable?
	• Planned speaker compensation will result in speaker exceeding cap	• Yes, speakers who have reached 75% of compensation cap are flagged by system	• Is the budgeted payment plus amount already paid going to result in a speaker exceeding cap?

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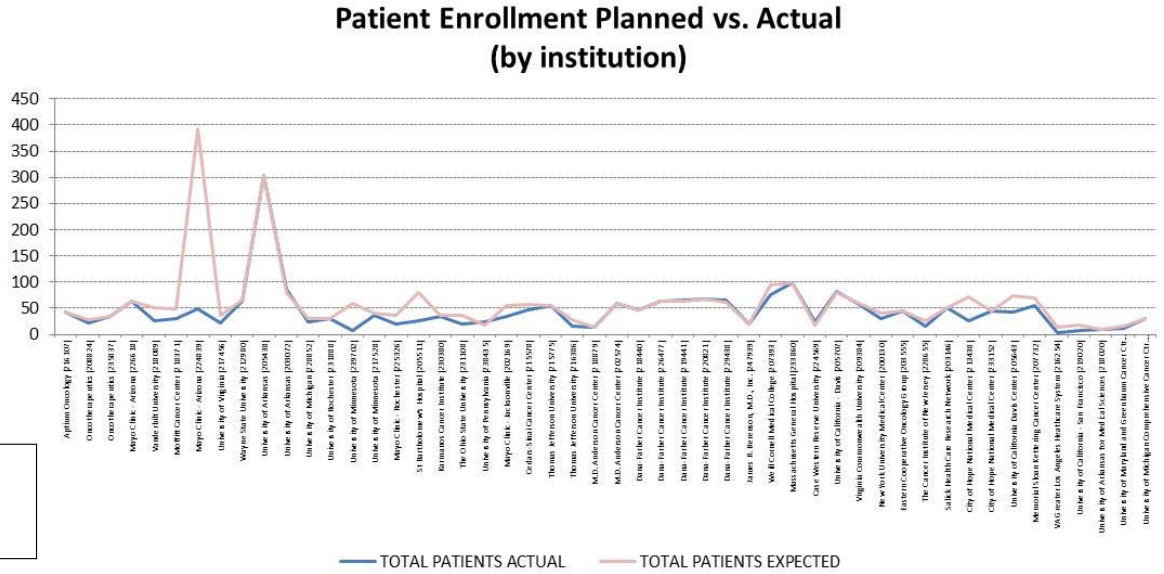
Data Analytics into Monitoring; Patient Enrollment Example

What is the number of patients enrolled planned vs. actual? What is the distribution by institution?

Answer:

- 48% of sites achieved enrollment targets; 52% did not.



Additional Observation

- Sample Base = 50 which represents 50 completed studies at 39 unique sites. The analysis excludes active studies.

Summarizing Process Results; An example

Summary of Results:

For closed studies, 48% of sites/PIs achieved enrollment targets; 52% did not.

- 26 studies had actual patient enrollment less than planned enrollment. Of the 26 studies, 11 studies either received a payment that was >50% of the grant total and/or enrolled <50% of planned patients.
- Two studies were closed (with no payments made) that had less than 50% of the planned enrollment.

Consider the following additional procedures for inquiry:

- Review studies where enrollment was less than plan to confirm study objectives are not compromised (e.g., statistical significance) focusing on studies where payment was made or planned enrollment didn't reach 50% (or another threshold) of plan.

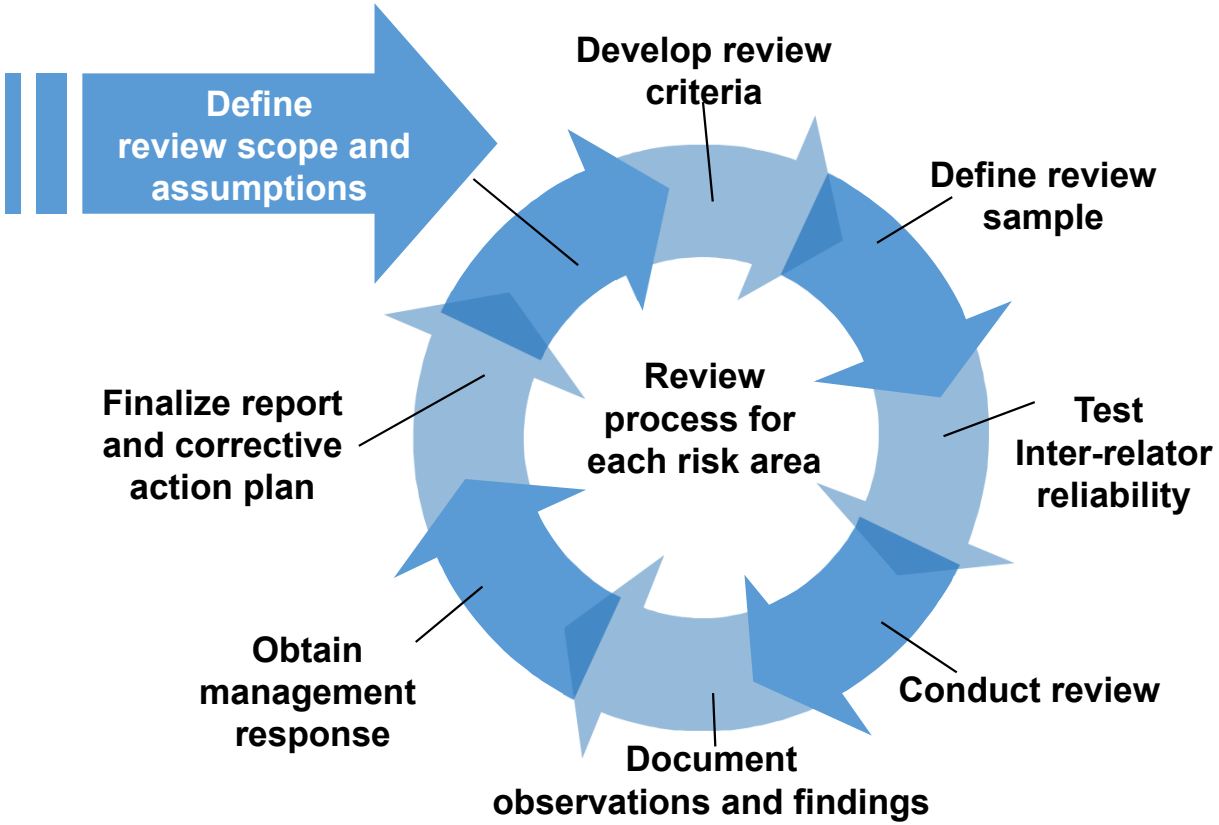
Consider the following policy changes or audit and monitoring procedures:

- Suggest new/revised policy on the use of low enrolling sites as defined by enrolling less than 50% of plan.

Analytic Recommendation:

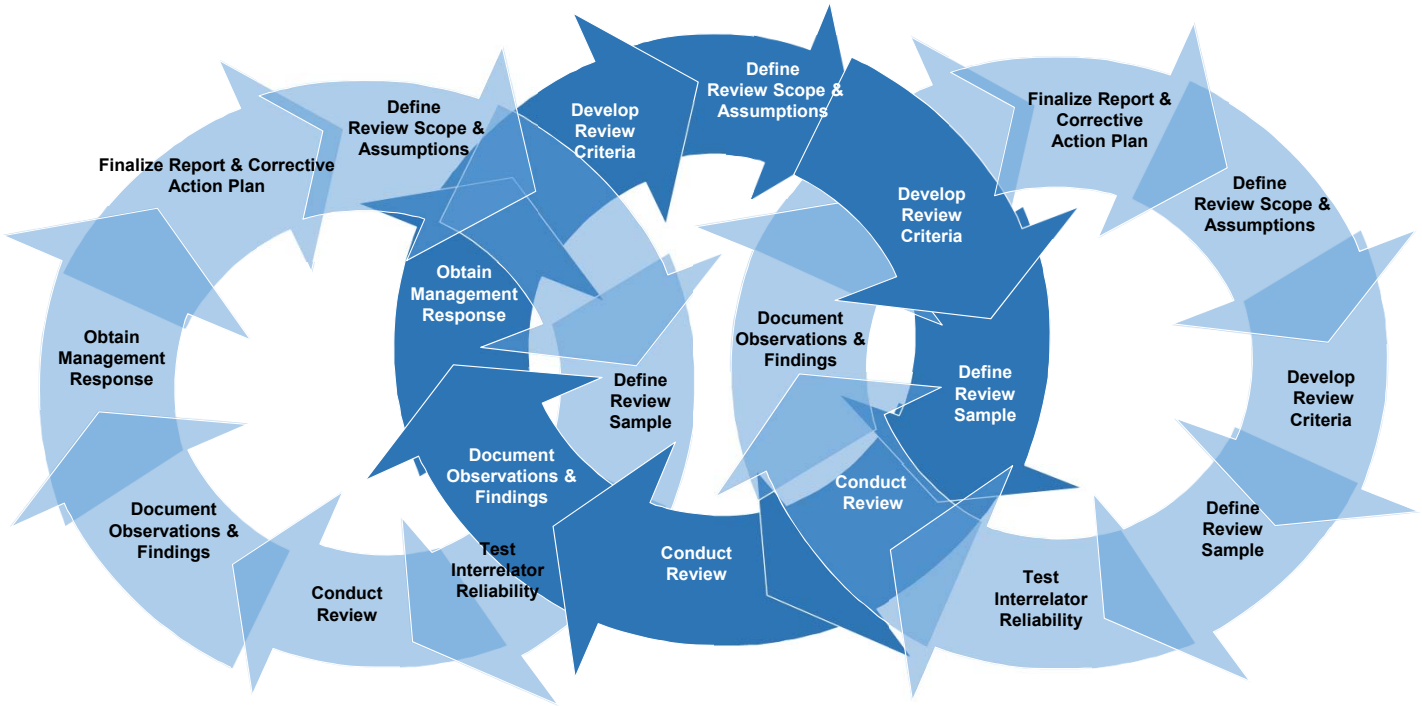
- Recommend enabling future analytic showing % planned enrollment for all studies (not just closed) and monitoring this monthly or quarterly to allow follow up with sites that are falling behind on enrollment targets.

The pilot areas turn into….



….A monitoring process

Monitoring never ends…each review leads to the next, and the monitoring plan and unplanned issues drive additional monitoring activities. It is a continuous process…



Monitoring Summary

- Defining Objectives and Scope is Key
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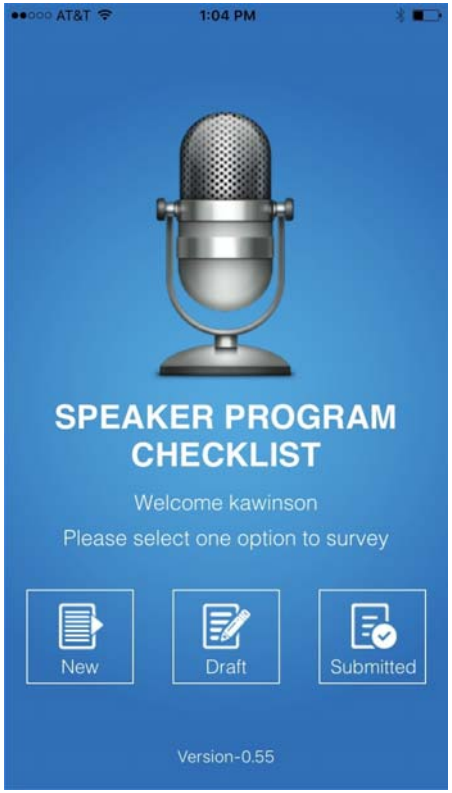
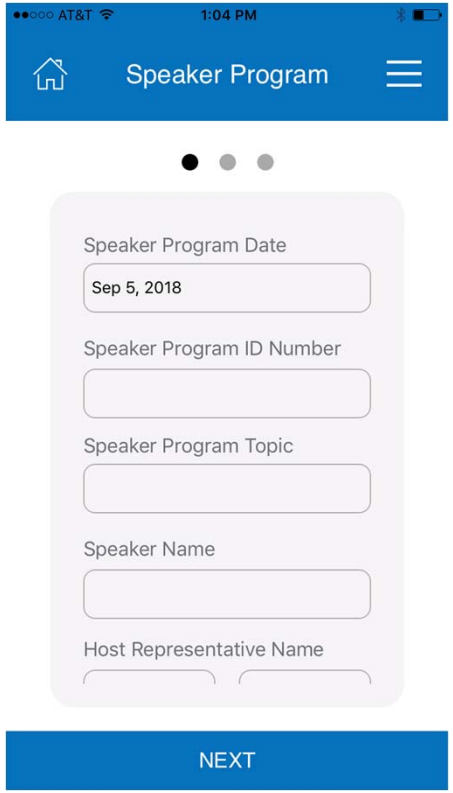
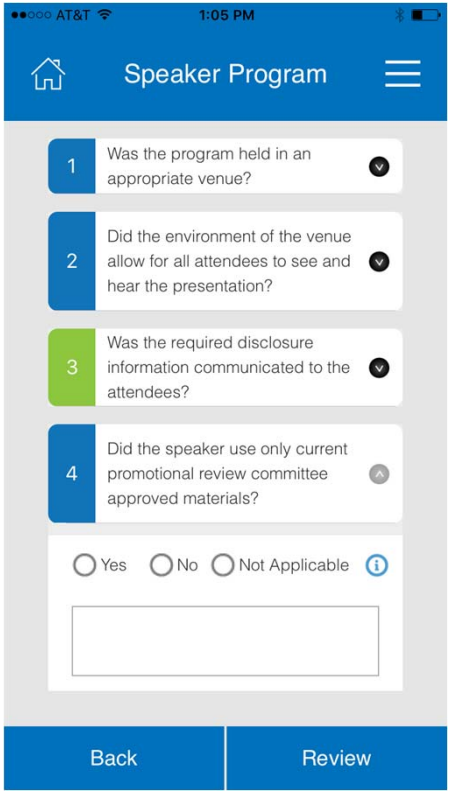
Example of current monitoring approach: Applying technology through ‘Field Monitoring App’

Field Monitoring App







Field Monitoring App – Efficiencies

- No need for computers in the field
- Quickly and easily review with reps before monitoring activity
- Data collected in one database and fed into case management system
  - Document management
  - Remediation and follow-up
  - Analytics
  - Sample selection/Event Prioritization
- Streamlined tracking of open observations and remediation
- More timely close-out process
- Ease of use and seamless process for “guest” monitors

Field Monitoring App Information

Program Details

Speaker Program Date	Oct 30, 2018
Speaker Program Id Number	1234
Speaker Program Topic	Multiple Myeloma
Speaker Name	John Doe
Host Representative FirstName	Jane
Host Representative LastName	Doe
Host Representative Title	Medical Liaison
Promotional Review Commitee	12345
Host Representing Territory	Northeast
Host Representing District	Test
Host Representing District	Jane

Host Representing District	Doe
Monitor Name	Ed Rielly
Total Number Of Attendees	7
Speaker Program Start Time	09:00 AM
Speaker Program End Time	10:00 AM
Program Status	Occurred
Franchise	Hematology / Oncology
Speaker Program Subject	Disease-State
Speaker Program Format	LiveSpeakerProgramInOffice
Speaker Program Type	HCPSpeakerProgramTraditional
Speaker Program Meal	Lunch
Venue Name	Grand Summit
Venue City	Summit
Venue State	NJ
Checklist Comments	Comments...

Questions

1- Was the program held in an appropriate venue?
Yes

2- Did the environment of the venue allow for all attendees to see and hear the presentation?
Yes

3- Was the required disclosure information communicated to the attendees?
Yes

4- Did the speaker use only current promotional review committee approved materials?
Yes

5- Was the information presented by the speaker consistent with the approved materials and applicable speaker training?
Yes

6- Were there any off-label questions from an attendee?
No

7- Did the Celgene employee distribute only current approved materials based on the topics discussed?
Yes

8- If applicable, were all REMS-related questions appropriately addressed?
N/A

9- If applicable, were all adverse events related to the use of a Celgene product reported in accordance with Celgene policy?
N/A

10- Did the program length, including any question and answer session, satisfy the time requirement?
Yes

11- Was the Minimum Appropriate Attendee Requirement satisfied?
Yes

12- Did all Celgene attendees participate in an appropriate capacity based on their role in the organization?
Yes

13- Did all attendees sign-in on either a hard copy or electronic sign-in sheet?
Yes

14- Was the meal modest by local standards?
Yes

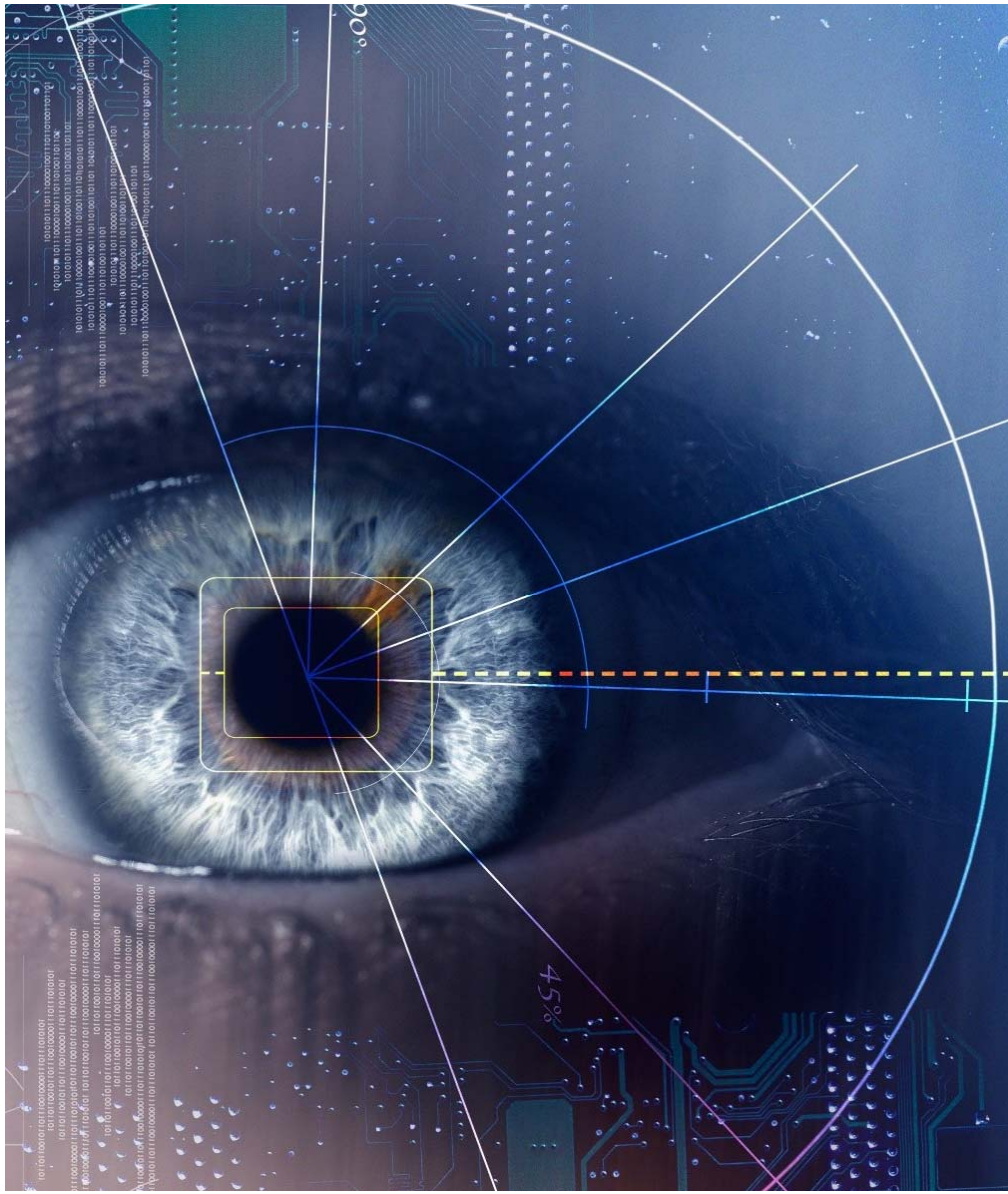
15- Did the program adhere to the established cost-per-person meal limit?
Yes

16- Was the meal provided without an entertainment or recreational component?
Yes

17- Were additional take-out meals prohibited?
N/A

18- Were there any additional compliance observations not included in the above questions?
No

Review of Corporate Integrity Agreements – Emerging Areas



Charity Foundation Donations

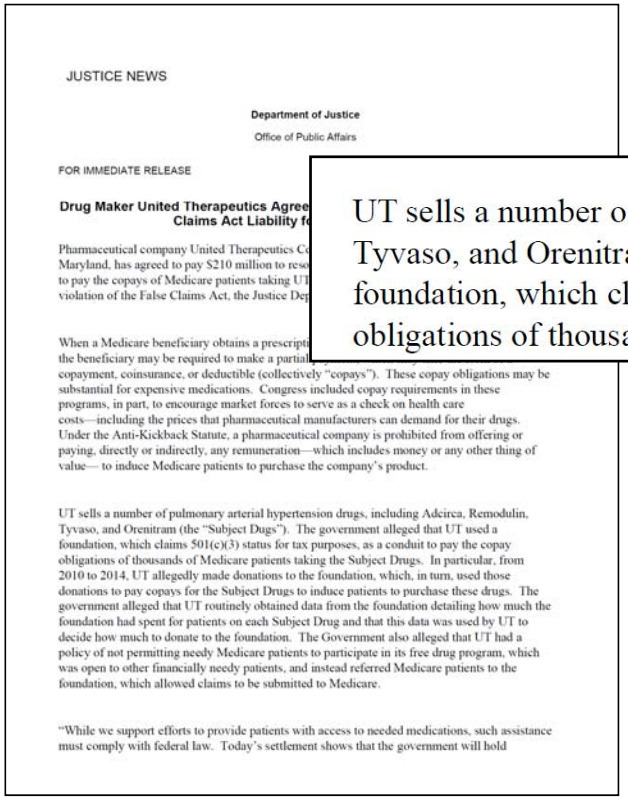
- **Lundbeck (June 2018)**
  - The American subsidiary of Danish drugmaker H. Lundbeck A/S reached an agreement in principle to settle an investigation into its donations to independent charity patient assistance programs
  - Lundbeck will pay $52.6 million
  - The agreement does not include any admission by Lundbeck LLC that it violated any law
  - Lundbeck had received a subpoena from the U.S. attorney's office in Boston "relating to an investigation of payments to charitable organizations providing financial assistance to patients taking Lundbeck products" and to the sale, marketing and related practices with its Northera and Xenazine products.
- **Jazz Pharmaceuticals (May 2018)**
  - According to a May 8 filing with the U.S. Securities and Exchange Commission, Ireland's Jazz Pharmaceuticals PLC agreed to pay $57 million to resolve a DOJ investigation into its purported financial support of nonprofits that help Medicare patients cover out-of-pocket drug costs.

Charity Foundation Donations

- **Additional Cases**
  - Approximately 20 companies being investigated by DoJ for similar donations
  - Additional announcements expected
- **Other Settlements**
  - Pfizer (May 2018)
    - $23.8 million
    - Settlement focused on donations to independent charity patient assistance programs
  - United Therapeutics (December 2017)
    - $210 million
    - Settlement focused on donations to independent charity patient assistance programs
  - Aegerion Therapeutics (September 2017)
    - $35 million
    - Settlement resolved allegations beyond donations to independent charity patient assistance programs

United Therapeutics ("UT")

Department of Justice Press Release



JUSTICE NEWS

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE

Drug Maker United Therapeutics Agree
Claims Act Liability f

Pharmaceutical company United Therapeutics C
Maryland, has agreed to pay $210 million to res
to pay the copays of Medicare patients taking U
violation of the False Claims Act, the Justice De

When a Medicare beneficiary obtains a prescript
the beneficiary may be required to make a partial
copayment, coinsurance, or deductible (collectively "copays"). These copay obligations may be substantial for expensive medications. Congress included copay requirements in these programs, in part, to encourage market forces to serve as a check on health care costs—including the prices that pharmaceutical manufacturers can demand for their drugs. Under the Anti-Kickback Statute, a pharmaceutical company is prohibited from offering or paying, directly or indirectly, any remuneration—which includes money or any other thing of value— to induce Medicare patients to purchase the company's product.

UT sells a number of pulmonary arterial hypertension drugs, including Adcirca, Remodulin, Tyvaso, and Orenitram (the "Subject Dugs"). The government alleged that UT used a foundation, which claims 501(c)(3) status for tax purposes, as a conduit to pay the copay obligations of thousands of Medicare patients taking the Subject Drugs. In particular, from 2010 to 2014, UT allegedly made donations to the foundation, which, in turn, used those donations to pay copays for the Subject Drugs to induce patients to purchase these drugs. The government alleged that UT routinely obtained data from the foundation detailing how much the foundation had spent for patients on each Subject Drug and that this data was used by UT to decide how much to donate to the foundation. The Government also alleged that UT had a policy of not permitting needy Medicare patients to participate in its free drug program, which was open to other financially needy patients, and instead referred Medicare patients to the foundation, which allowed claims to be submitted to Medicare.

"While we support efforts to provide patients with access to needed medications, such assistance must comply with federal law. Today's settlement shows that the government will hold

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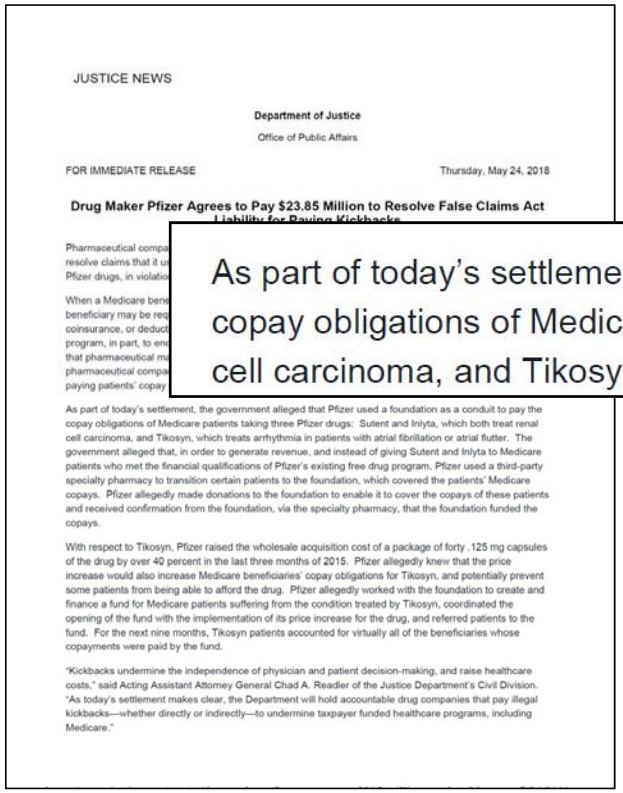
United Therapeutics ("UT")

Civil Settlement Agreement Covered Conduct

- **Data from Caring Voice Coalition ("CVC")**
  - From February 2010 through January 2014, UT routinely obtained data from CVC detailing how many patients on each Subject Drug CVC had assisted and how much CVC had spent on those patients.
  - In deciding whether and how much to donate to CVC, UT considered the revenue it would receive from prescriptions for Medicare patients who received assistance from CVC to cover their copays for the Subject Drugs.
  - UT used data from CVC to confirm that UT's revenue far exceeded the amount of UT's donations to CVC.
- **Directing Medicare Patients to CVC**
  - UT had a policy of not permitting Medicare patients to participate in its free drug program, which was open to other financially needy patients, even if those Medicare patients could not afford their copays for UT drugs
  - To generate revenue from Medicare and to induce purchases of the Subject Drugs, UT referred Medicare patients prescribed the Subject Drugs to CVC, which resulted in claims to federal healthcare programs to cover the cost of the drugs

Pfizer
Department of Justice Press Release



JUSTICE NEWS

Department of Justice
Office of Public Affairs

FOR IMMEDIATE RELEASE Thursday, May 24, 2018

Drug Maker Pfizer Agrees to Pay $23.85 Million to Resolve False Claims Act Liability for Paying Kickbacks

Pharmaceutical compa
resolve claims that it u
Pfizer drugs, in violatio

When a Medicare bene
beneficiary may be req
coinsurance, or deduct
program, in part, to enc
that pharmaceutical m
pharmaceutical compa
paying patients' copay

As part of today's settlement, the government alleged that Pfizer used a foundation as a conduit to pay the copay obligations of Medicare patients taking three Pfizer drugs: Sutent and Inlyta, which both treat renal cell carcinoma, and Tikosyn, which treats arrhythmia in patients with atrial fibrillation or atrial flutter. The government alleged that, in order to generate revenue, and instead of giving Sutent and Inlyta to Medicare patients who met the financial qualifications of Pfizer's existing free drug program, Pfizer used a third-party specialty pharmacy to transition certain patients to the foundation, which covered the patients' Medicare copays. Pfizer allegedly made donations to the foundation to enable it to cover the copays of these patients and received confirmation from the foundation, via the specialty pharmacy, that the foundation funded the copays.

With respect to Tikosyn, Pfizer raised the wholesale acquisition cost of a package of forty .125 mg capsules of the drug by over 40 percent in the last three months of 2015. Pfizer allegedly knew that the price increase would also increase Medicare beneficiaries' copay obligations for Tikosyn, and potentially prevent some patients from being able to afford the drug. Pfizer allegedly worked with the foundation to create and finance a fund for Medicare patients suffering from the condition treated by Tikosyn, coordinated the opening of the fund with the implementation of its price increase for the drug, and referred patients to the fund. For the next nine months, Tikosyn patients accounted for virtually all of the beneficiaries whose copayments were paid by the fund.

"Kickbacks undermine the independence of physician and patient decision-making, and raise healthcare costs," said Acting Assistant Attorney General Chad A. Readler of the Justice Department's Civil Division. "As today's settlement makes clear, the Department will hold accountable drug companies that pay illegal kickbacks—whether directly or indirectly—to undermine taxpayer funded healthcare programs, including Medicare."

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Pfizer
Civil Settlement Agreement Covered Conduct

- **Directing Medicare Patients to PANF**
  - Pfizer contracted with Advanced Care Scripts ("**ACS**") to act as a third-party specialty pharmacy for Sutent and Inlyta patients prescribed those products, including Medicare patients
  - Instead of giving away Sutent and Inlyta for free to Medicare patients who met the financial qualifications of Pfizer's existing free drug program, Pfizer worked with ACS to transition some portion of these patients to PANF
  - Pfizer made donations to PANF and received data from PANF, via ACS, confirming that PANF funded the Medicare copays of Sutent and Inlyta patients.

Pfizer
Civil Settlement Agreement Covered Conduct

- **Influencing Disease State Fund**
  - Pfizer raised the wholesale acquisition cost of a package of Tykosin capsules of the drug from $220.24 to $317.15 in the last three months of 2015.
  - Knowing the price increase would increase Medicare beneficiaries' copay obligations (which could result in more Medicare patients needing financial assistance to fill their Tikosyn prescriptions), Pfizer worked with PANF to create and finance a fund for Medicare patients being treated for arrhythmia with atrial fibrillation or atrial flutter
  - Pfizer coordinated the timing of the opening of PANF's fund for these patients with the implementation of the Tikosyn price increase,
  - Pfizer then began referring to PANF any Medicare patients who needed financial assistance to meet their newly-increased copays for the drug
  - For the next nine months, Tikosyn patients accounted for virtually all of the beneficiaries of PANF's fund for Medicare patients being treated for arrhythmia with atrial fibrillation or atrial flutter.

Review of Corporate Integrity Agreements – Considerations for Monitoring

Corporate Integrity Agreement

United Therapeutics and Pfizer (General Requirements)

- **Term** – 5 years
- **Covered Persons –** Employees and vendors who engage in activities related to:
  - Promotion
  - Donations to independent charity PAPs
  - Patient assistance programs (free drugs)
  - Copay/coupon programs
- **Compliance Personnel –** Compliance Officer and Compliance Committee
- **Board Duties** – Training, Oversight and Resolution
- **Senior Executives/Leaders –** Management Certifications
- **Outside Reviews –** Independent Review Organization
- **Reporting to OIG:**
  - Reportable Events
  - Government Investigations and Legal Proceedings
  - Implementation and Annual Reports
  - Changes to Compliance Officer, Committee, Board members, etc.

Corporate Integrity Agreement

United Therapeutics and Pfizer (Donation Controls)

- **Independent Group**
  - Group responsible for donations separate from commercial business units (i.e., separate from commercial business units, sales and marketing)
- **Communications with Independent Charity PAPs**
  - Communications only between independent group and foundation regarding donations
  - Commercial organization not permitted to communicate with, influence, or be involved in any communications with, or receive information from Independent Charity PAPs
- **Budgets for Donations to Independent Charity PAPs**
  - Independent group must develop budget based on objective criteria and guidelines from legal/compliance
  - Commercial organization not permitted to have any involvement in budget or allocation process
  - Executive leadership permitted to approve overall budget

Corporate Integrity Agreement

United Therapeutics and Pfizer (Donation Controls)

- **Criteria for Donations**
  - Independent group responsible for developing objective criteria (with input from Legal/Compliance) and reviewing and approving donation decisions
    - Establishing/ Defining Fund: No control/influence over the identification, delineation, establishment, or modification of any specific disease funds operated by the Independent Charity PAP.
    - Criteria for Eligibility: No direct or indirect influence or control over the Independent Charity PAP's process or criteria for determining eligibility of patients who qualify for its assistance program
    - Data: No solicitation of data or information from an Independent Charity PAP (either directly, indirectly, or through third parties) to correlate the amount or frequency of its donations with the Independent Charity PAP's support for Company's products or services; and
    - Single Drug Fund/ Company-Only Products: No donations for a disease state fund that covers only a single product or that covers only the Company's products.

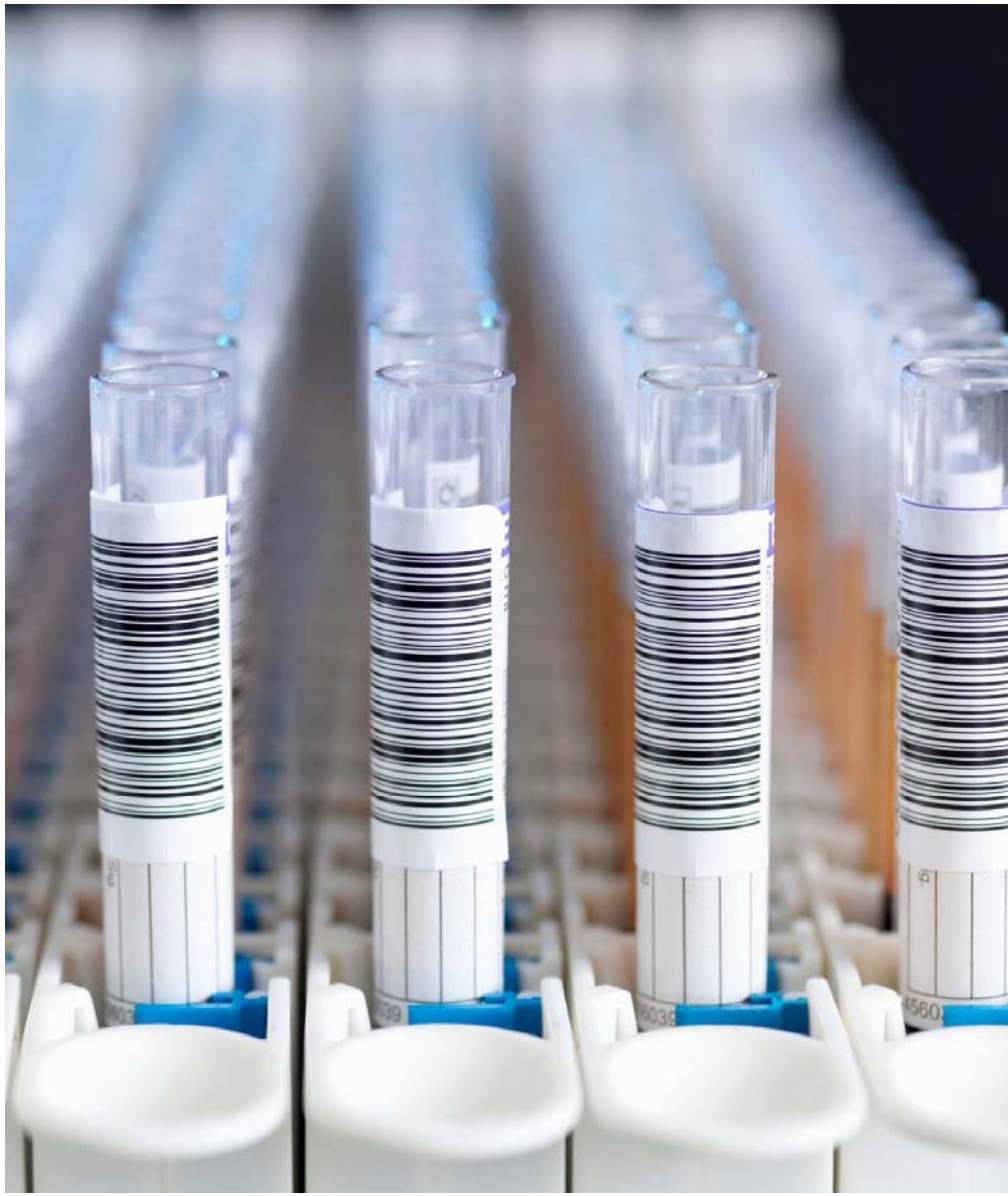
Corporate Integrity Agreement
Pfizer (Monitoring Program)

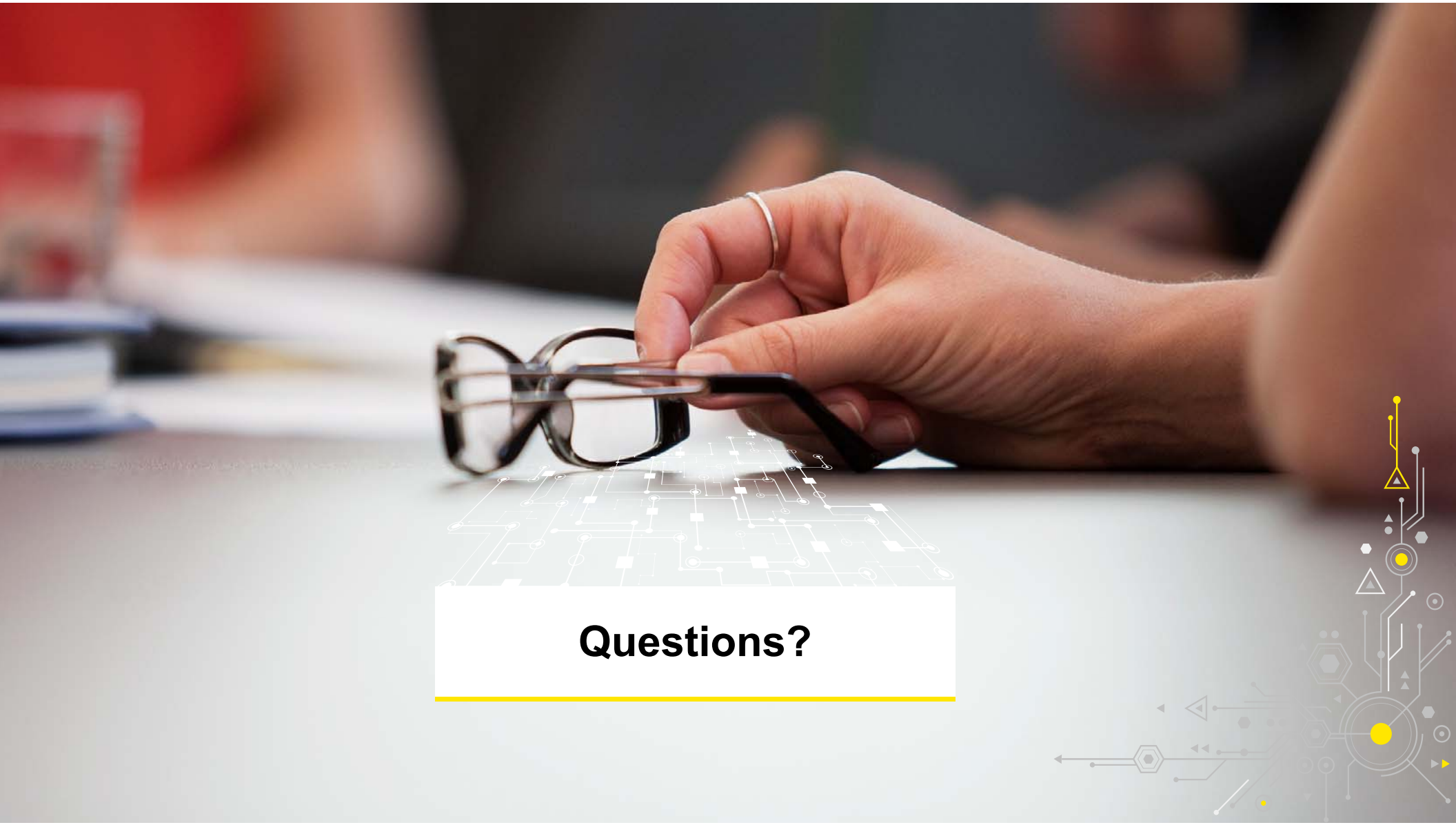
- **Purpose of Review**
  - To assess whether the activities were conducted in a manner consistent with Company's policies and procedures described above and with OIG guidance
- **Compliance Department**
  - Compliance department or other appropriate personnel conduct annual monitoring of 10 or 50% (whichever is a greater number) of donations to disease state funds
- **Risk-Based and Random Selection**
  - Select on both a risk-based targeting approach and a random sampling approach.
- **Information/Documents to Review**
  - Budget documents
  - Documents relating to the decision to provide donations to a particular Independent Charity PAP
  - Written agreements in place between Company and the Independent Charity PAPs
  - Correspondence, emails, and other documents reflecting communications and interactions between Company and the Independent Charity PAPs and
  - Other available information relating to the arrangements and interactions

Corporate Integrity Agreement
Pfizer (Monitoring Program)

- **Escalation:**
  - In the event that a compliance issue, Pfizer shall address the incident consistent with established policies and procedures for the handling of compliance issues
  - Findings shall be made and all necessary and appropriate responsive action (including disciplinary action) and corrective action shall be taken, including the disclosure of Reportable Events
  - Results from the Independent Charity PAP Review Program, including the identification of potential violations of policies and procedures, shall be compiled and reported to the Compliance Officer for review and follow-up as appropriate
  - Any compliance issues identified during the PAP Review Program and any corrective action shall be recorded in the files of the Compliance Officer
  - Pfizer shall include a summary of the monitoring program in the Implementation Report.
  - Pfizer shall include a description of any changes to the monitoring program and the results of the monitoring program as part of each Annual Report

Life Post-CIA: Discussion





Questions?