

## White Paper



### HCP Public Disclosure Reporting and Compliance A Perspective

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The Life Science Industry and HealthCare Professionals (HCPs) have a symbiotic relationship. Their relationship provides a strong foundation to providing quality health care and advancing the boundaries of medical research. Healthcare professionals (HCPs) through their clinical experience, provide guidance on patient needs and clinical data. This invaluable input is a guiding force to advancing medical research and development and the advocacy of optimal medical treatment for patients

There are many situations in which an economic exchange between Life Sciences organizations and HCPs can occur such as conference related meals and entertainment, product related promotional materials, sponsored research and medical education support to name a few. Over the years, companies have established Fair Market Value guidelines to ensure that payments to HCPs are fair and appropriate to services provided.

This expert opinion outlines the challenges facing the Life Sciences industry in ensuring HCP Spend disclosure compliance, core considerations to enable a single view of all payments made to individual HCPs and how a focused reporting solution can support increased HCP reporting efficiency, reduction in manual reporting errors and improvements in validation and traceability of data changes.

## Industry HCP Public Disclosure Reporting Requirements

At a high level, there are three primary Life Sciences requirements for HCP public disclosure reporting:

- **Compliance Requirements** - State and Federal legislators have enacted laws/regulations which require that Life Sciences companies disclose and report their HCP related expenditure. The Physician Payment Sunshine Act (federal legislation) proposes HCP spend disclosure across all states. This is likely to impact every pharmaceutical and medical device company in the US. Companies need to comply with these disclosure laws and there are punitive actions for non compliance.
- **Planning and Budgeting Requirements** - Expenditure reporting enables a company to have potential benefits like a more accurate view of the customer, increased visibility of the Sales and Marketing spend, and reporting of additional information for Internal Audit purposes.
- **User adoption of new reporting needs** - Life Sciences companies are increasingly seeking to build HCP reporting solutions which should be reliable, facilitate validation, improve efficiency in the HCP expenditure and reduce manual error.

## Industry Challenges

Today, regulatory mandates have called for increased transparency and obligation on the part of Life Sciences companies to disclose payments made to HCPs. We can summarize some of the core challenges faced by Life Sciences companies for HCP Public Disclosure reporting as follows:

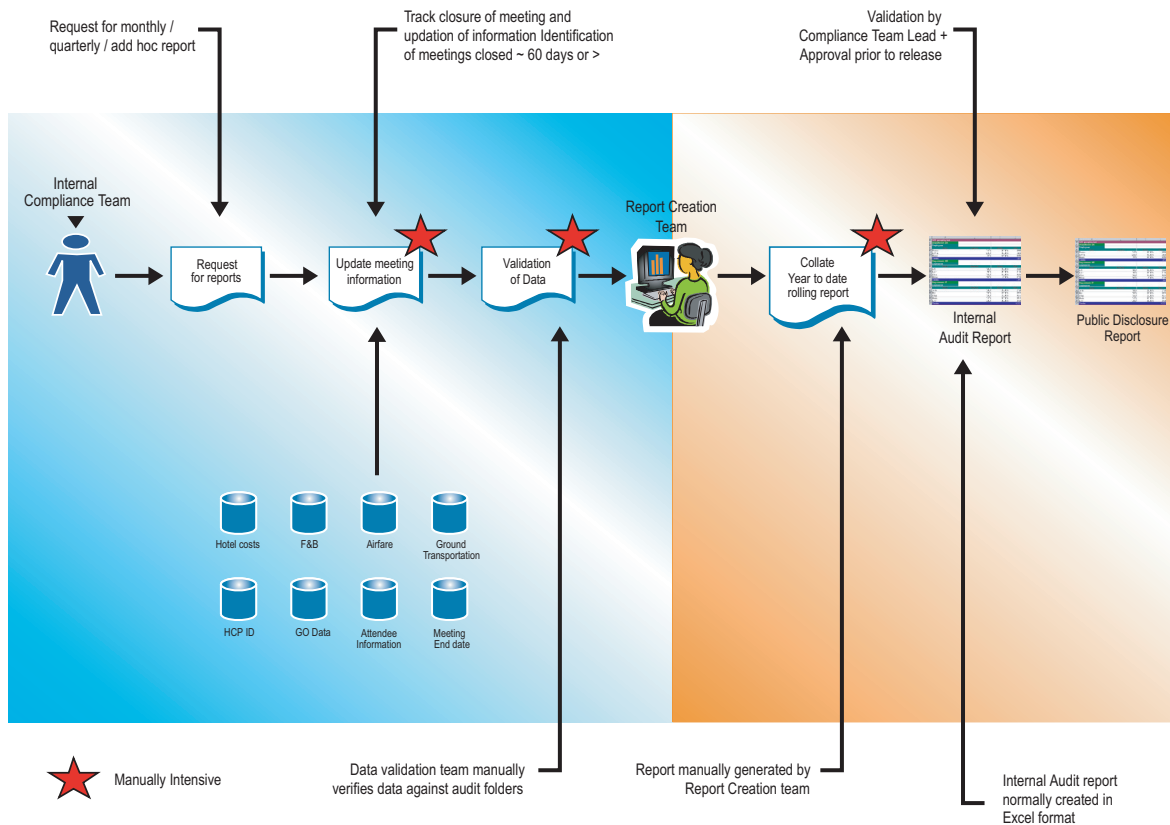
- Currently for most companies it is a manually intensive process to gather, consolidate, validate and report total physician spend
- Ability to create a single view of HCP across variable systems and expenditure transactions
- Identification of individual HCPs across multiple affiliations with hospitals, clinics and universities
- Master Data Management challenges - Occurrence of duplicate HCP IDs, missing IDs
- Potential error in calculations of key reporting metrics
- Identifying expense outliers can be difficult and time consuming
- Tracking the expenditure on HCPs by third party vendors on behalf of the company
- HCP ID reconciliation and prevention of HCP ID duplication following mergers and acquisitions.
- Availability of SOPs and links to user training for HCP reporting requirements In addition to the challenges discussed, another important challenge would be to establish business rules to address varied reporting laws and compliance requirements for HCP spend reporting.

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## Current HCP Public Disclosure Reporting Process

In the current scenario, industry regulatory bodies or internal compliance teams request for reports from Life sciences companies on a periodic basis which may be quarterly or monthly. A common practice today is for life sciences companies to gather the total physician spend information, consolidate, validate and report it in the form of Excel based reports.

## A look at a representative current state reporting process



### Issues observed with current reporting process:

- Manually intensive process to gather, consolidate, validate and report total HCP spend
- Reports can take days or even weeks to be generated and validated
- Need to minimize potential error in calculations of key reporting metrics
- Identifying expense outliers difficult and time consuming
- Effort to gather and align the data to individual HCPs becomes difficult with the occurrence of missing HCP IDs
- Traceability of information is often time consuming in response to audit needs

## An approach to optimize the HCP Public Disclosure reporting

Keeping in mind current industry challenges and requirements, an optimal HCP public disclosure solution should focus on three key industry requirements:



1. Increasing efficiency of the HCP spend reporting process

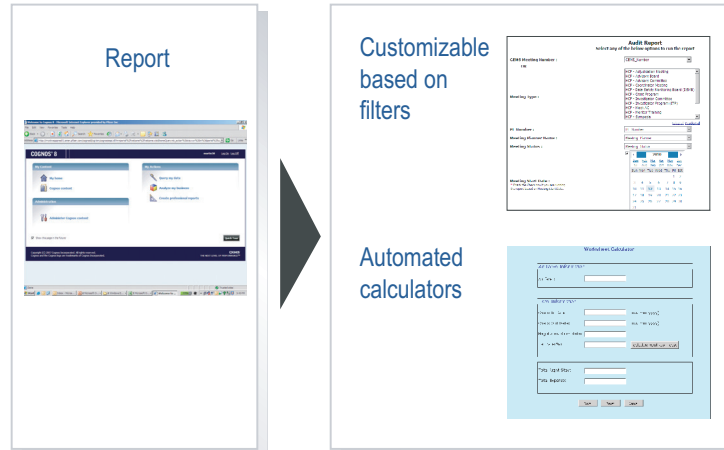
2. Minimizing errors in the reporting process

3. Supporting audit readiness of the reporting process

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Increasing efficiency of the HCP spend reporting process

The reporting solution should incorporate core business and functional requirements including requisite payment related fields, metrics, business rules.



Reports should have built in filters to customize reporting based on Meeting Planner name, Meeting Type (e.g. Advisory Board, Product launch, Symposia etc.), Date of meeting and Company Meeting ID.

The reports should also be automatically generated specifically for HCP spend public disclosure and audit purposes with the ability to track meetings by date, type, meeting planner and meeting status. The reports should also have a budgeting and cost savings focus - e.g. Report on HCP payments for cancelled programs, any spending on non-HCPs and non targets.

2

### Minimizing errors in the reporting process

The current state HCP Public Disclosure reporting process can be manually intensive where the meeting planners / report generation team often computes key spend expense details outside of the primary systems and manually enter details in the reports. This can increase the occurrence of errors both in calculations as well as at the physical entry level.

An optimal solution should incorporate the creation of automated calculators within the primary meeting management system / reporting system to enable traceability and accuracy of all calculations.

Additional recommendations would focus on improving operational metrics through dashboards and enablement of currency calculators to support reporting conversion of different currencies to \$ in international Hotel RFPs.

3

### Supporting audit readiness of the reporting process

The reporting solution should provide reports wherein an audit trail is built in to track changes made to individual fields. Through the audit trail, one can track changes made by field, date and person making the change. The solution should also provide for flagging of expense outliers to ensure better compliance and audit support.

The screenshot displays a software interface for 'Audit Readiness Support'. On the left, a vertical label reads 'Audit Readiness Support'. The main area is divided into two sections. The top section, titled 'Audit Trail Report', shows a table with columns for 'Field', 'Date', and 'Person'. The bottom section, titled 'Archived Reports', shows a stack of report thumbnails. To the right of the 'Archived Reports' section is a 'Notes' box with a legend for expense outliers:

- HCP Average F&B Spend > 500 \$
- HCP Average F&B Spend is NULL and Meeting is Attended
- Attendee Airfare > 800 \$
- Attendee Ground Transportation > 400 \$
- Attendee Total Hotel Room Cost > 800 \$
- Hotel Room Night Cost > 200 \$
- US Attendee with no HCP ID

Infosys also advocates the updation of reporting SOPs and process documentation to support training and prevention of workarounds in the report generation process.

## Conclusion

This expert opinion examined the current Life Science industry HCP Public Disclosure reporting requirements like compliance, planning, budgeting and user adoption of new reporting needs. We also looked at the current state report process and core reporting challenges that the industry faces today. It is extremely important in the design considerations of a new HCP reporting solution; that organizations should focus on increasing reporting efficiency, reduction in manual reporting errors and improvements in validation and traceability of data changes.

## About the Authors

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Sanjay has over 15 years experience consulting on business processes, technology and project management in the Life Sciences domain to help clients achieve process improvement, business transformation and improvement in business intelligence & CRM capabilities. Sanjay holds a Bachelors Degree in Pharmaceutical Sciences and an M.B.A. in Marketing

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Roopa has 6 years of experience in business requirements elicitation, business process analysis and modeling, design and testing of applications in Life Sciences and Healthcare domains. Roopa holds a Bachelors Degree in Electronics Engineering.



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