

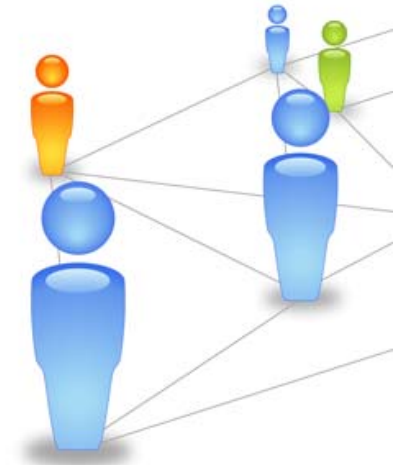
PRECONFERENCE: AGGREGATE SPEND AND DISCLOSURE 101



The Basics of Disclosure/Aggregate Spend Technology Solutions

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Sr Director, Compliance Solutions
Cegedim

March 9th, 2011



THIS IS THE INTRODUCTION COURSE - AGS101.

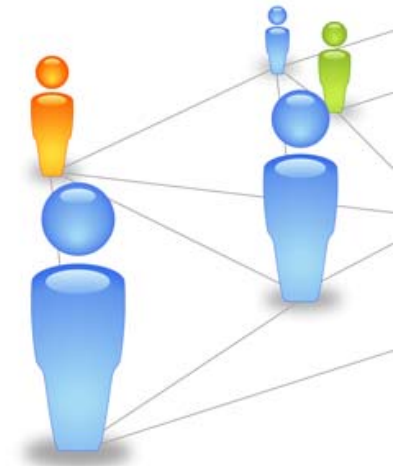
IF YOU ARE NOT REGISTERED FOR THIS COURSE YOU ARE IN THE WRONG ROOM.

THE CLASS SCHEDULES AND LOCATIONS ARE POSTED IN THE HALLWAY ...😊

Agenda



- Regulatory Compliance Trends
- Data Management Scope
- Technology Solution Capability
- Global Transparency



REGULATORY COMPLIANCE TRENDS

Increase in Aggregate Spend and Disclosure Laws



- **Transparency is becoming the rule**
 - Many states and federal government have enacted legislation regarding disclosure of promotional spend
 - Each law has different required information and report format
 - State and Federal Disclosure of Samples
- **New federal law adds layer of complexity**
- **Companies will be scrutinized more**
 - Spending information will now be available to public on the web

Other Considerations

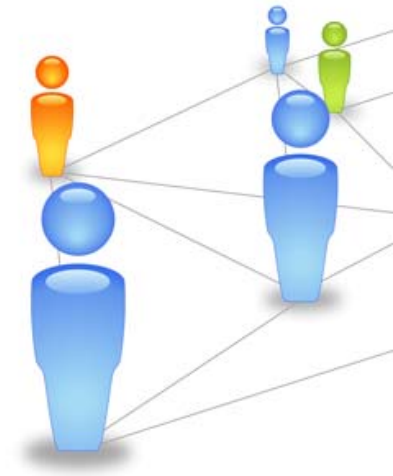


- **Global transparency trends**
- **PhRMA Code on Interactions with HCPs**
- **AdvaMed Code of Ethics**
- **Anti Bribery regulations (i.e., US Foreign Corrupt Practices Act, UK Bribery Act)**
- **OECD Convention (36 countries)**
 - International anti-corruption instrument focused on the 'supply side' of the bribery transaction



ORGANISATION
FOR ECONOMIC
CO-OPERATION
AND DEVELOPMENT





DATA MANAGEMENT SCOPE

Transparency Mandates Accuracy



→ The Process

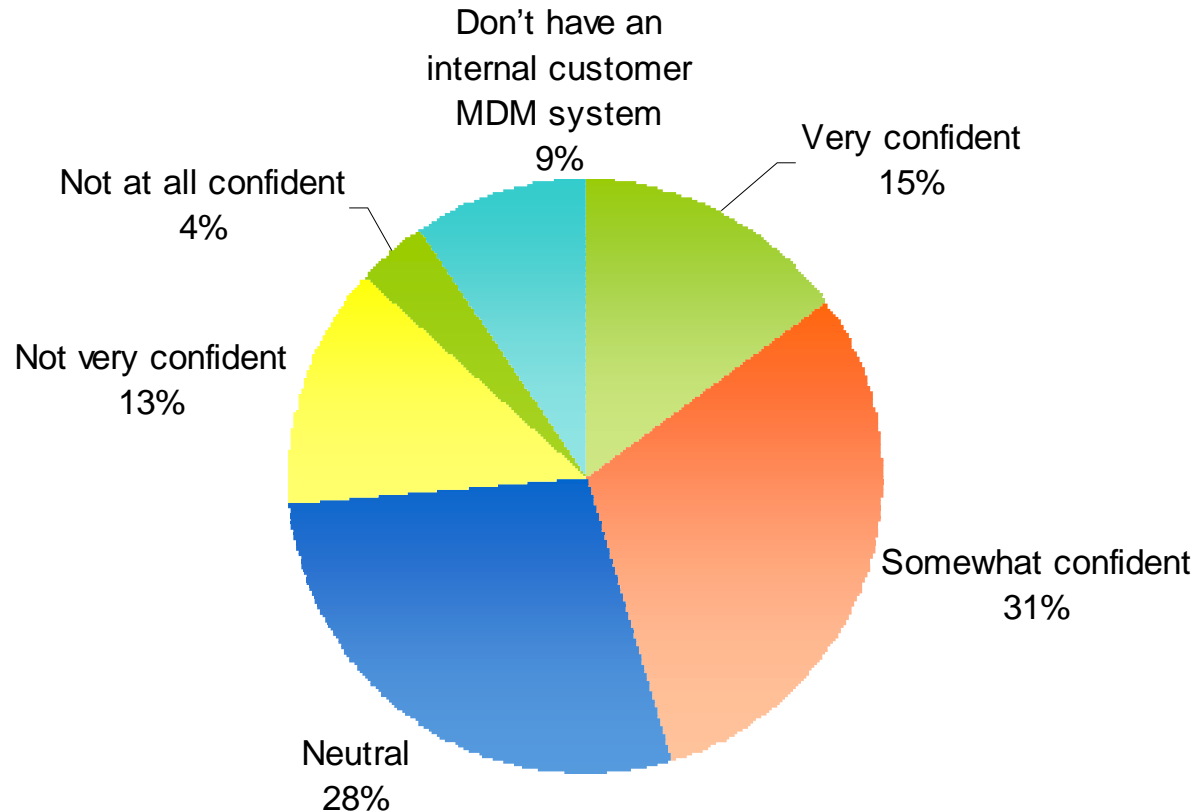
- Master data handling needs to operate at a more advanced level
 - Needs to become second nature for all the enterprise spend related systems



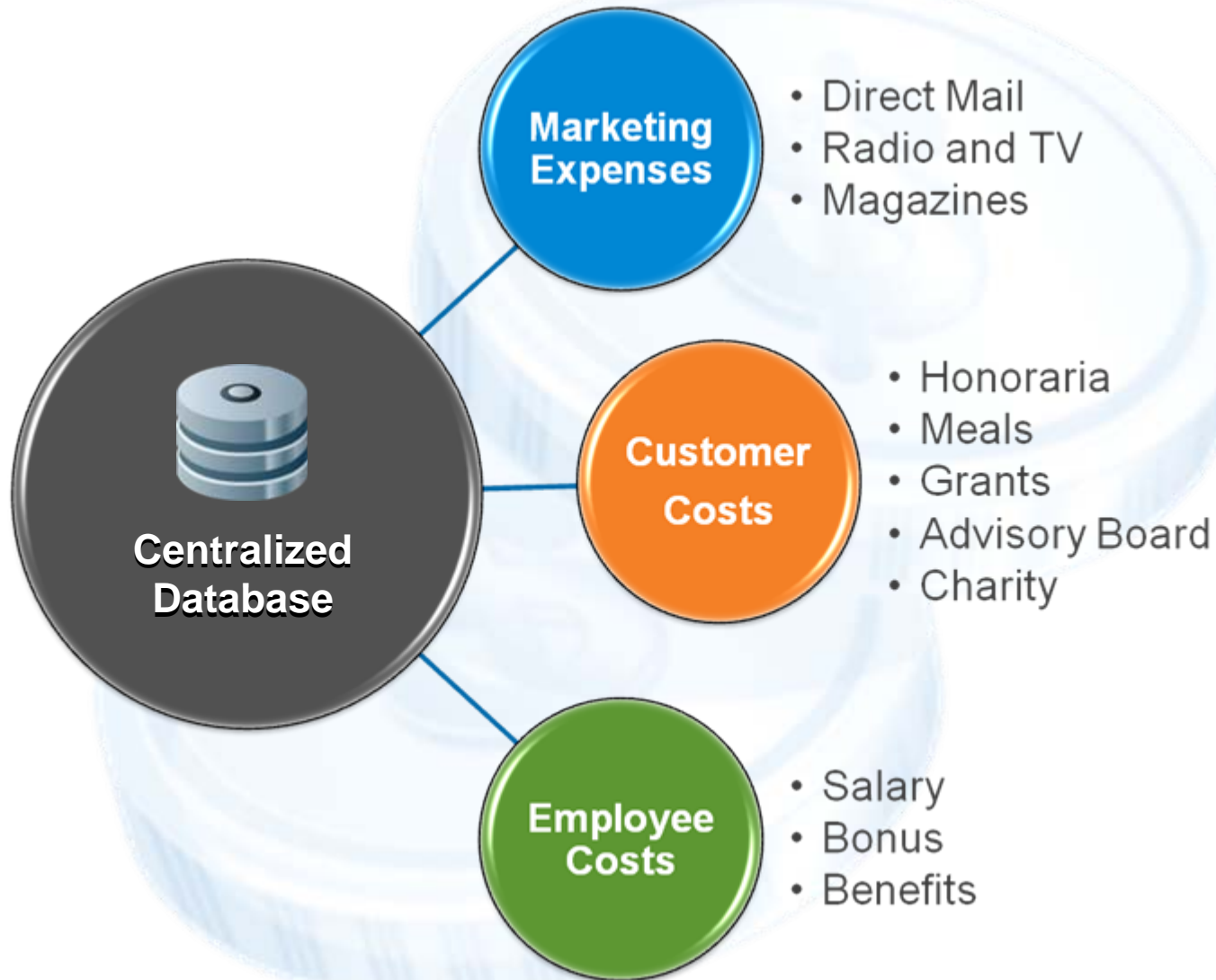
Companies' confidence in their customer data could be better in the US, according to 2010 survey



Level of confidence in the ability of your internal customer master management system to define the unique recipient records across all spend sources?



Consolidating All Expenses



Transparency is an Operational Challenge



Customer Engagement Types

Sales & Marketing

- Gifts, Meals, Entertainment
- S&M Customer expenses, samples
- Free for Service arrangements
- Advertising
- Patient education
- Conventions

R&D and Medical Affairs

- Clinical trials
- Free for Service arrangements
- Medical Liaison Customer Expenses
- Medical Publications
- Medical Information

Corporate Affairs

- Charitable Contributions
- Advocacy
- Corporate Memberships
- Grants
- Sponsorships
- Fellowships

Third Party Vendor/Partners

- Market Research
- Vendor-managed Programs
- CME
- Clinical trials

Geographies

Products

Business Units

Customers

Employees

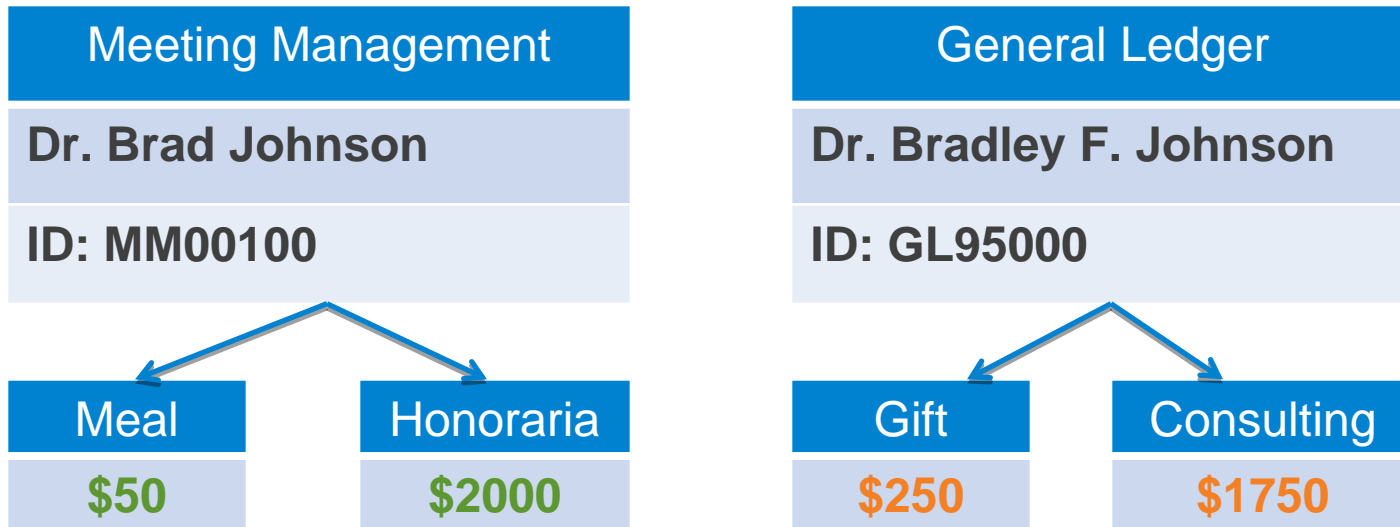
Vendors

Centralized Database

What If Your Systems Use Different Customer Lists?

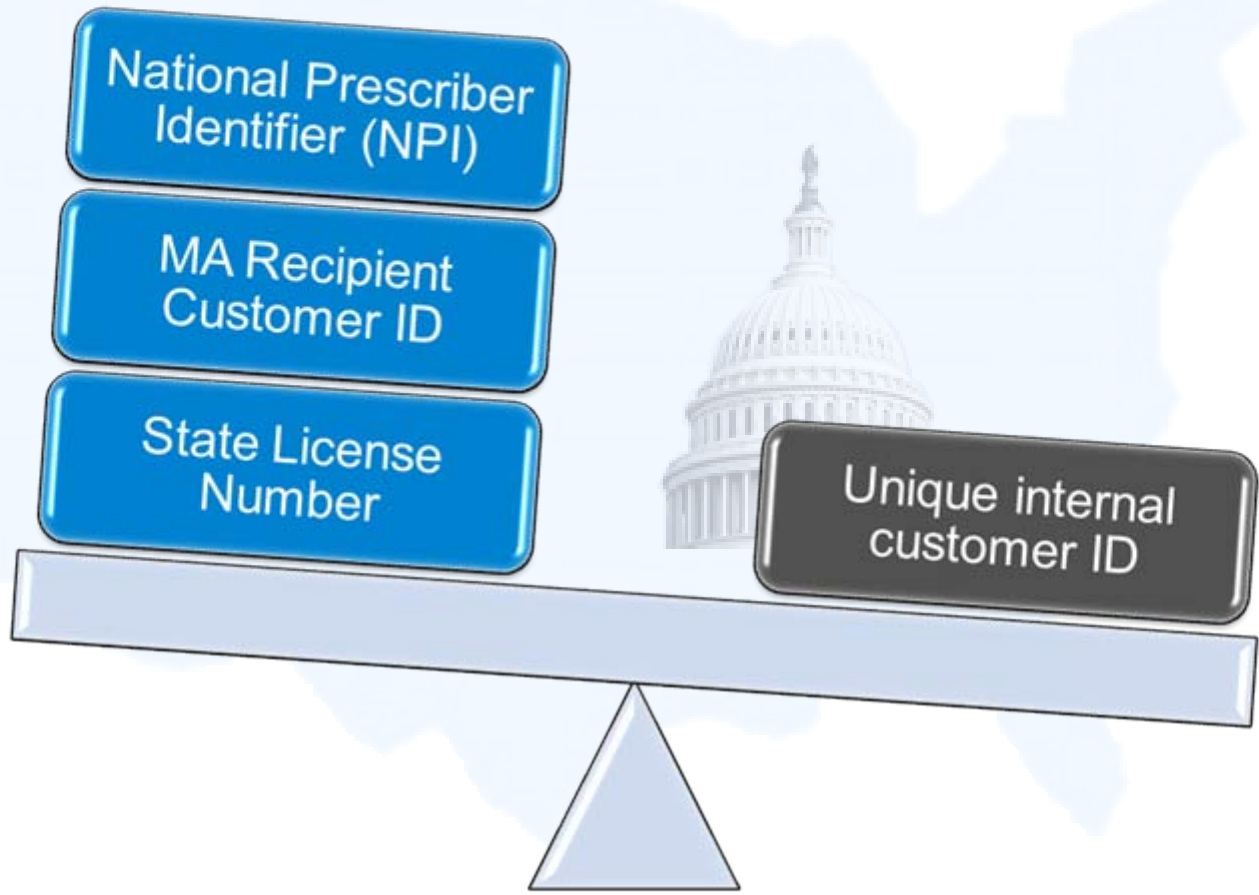


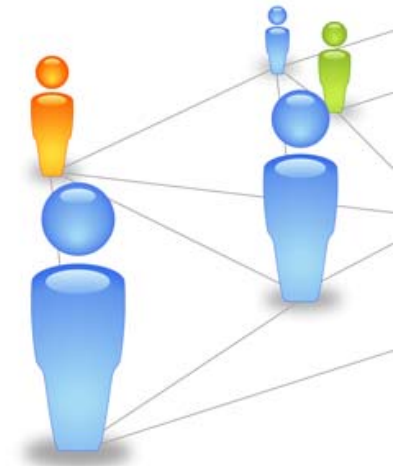
- Example: Does your Meeting Management system use the same customer identifier as your General Ledger system?



→ Total Reportable Spend: **\$2050** + **\$2000** = **\$4050**

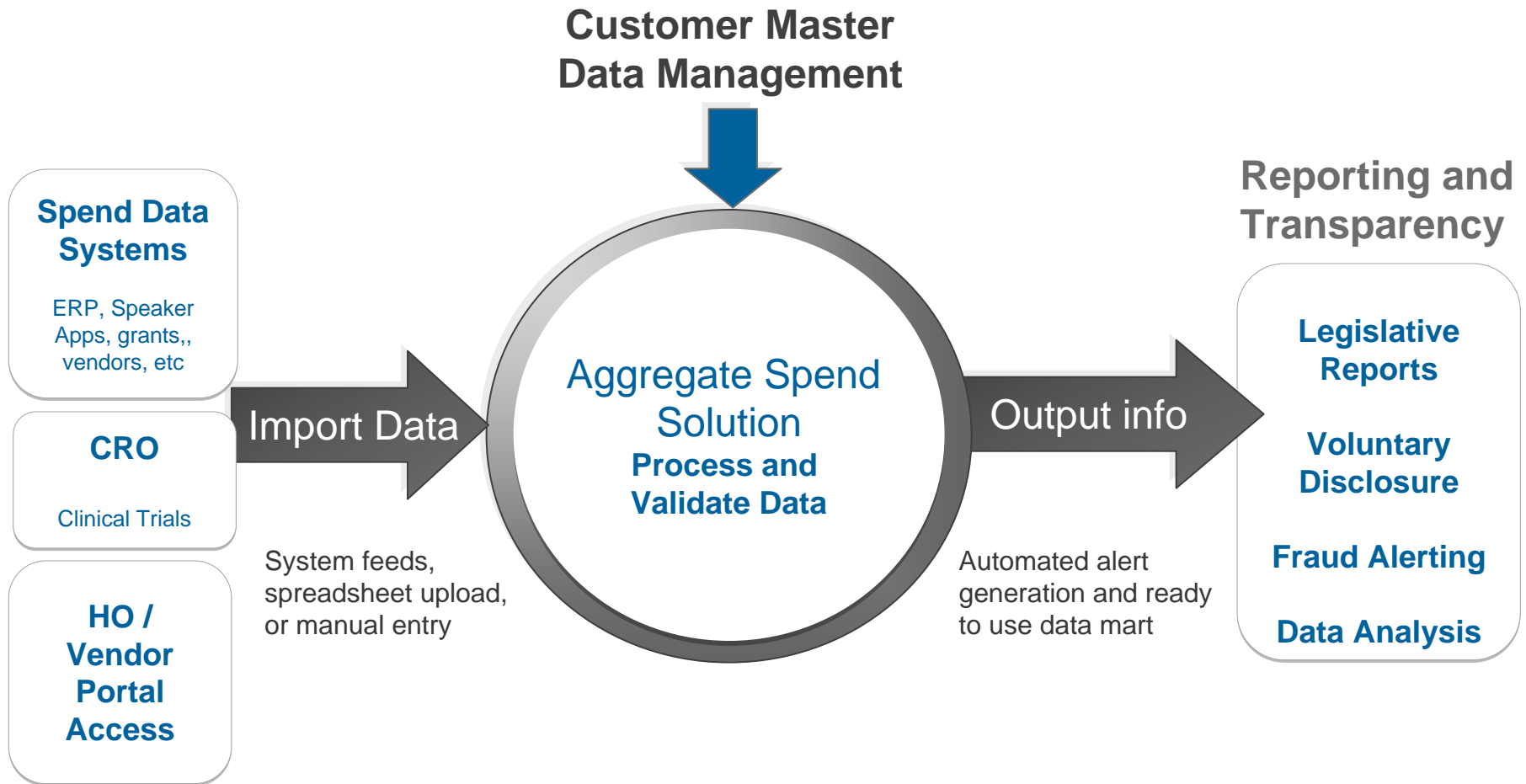
How do you handle State and Federal Identifiers?



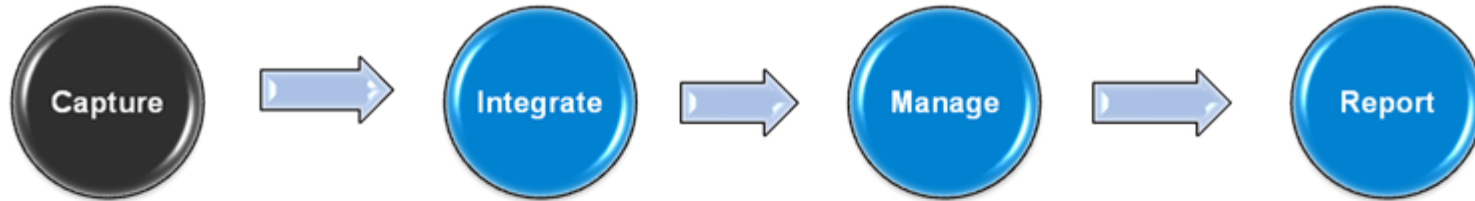


TECHNOLOGY SOLUTION CAPABILITY

Technology Overview



Aggregate Spend Solution –Capture

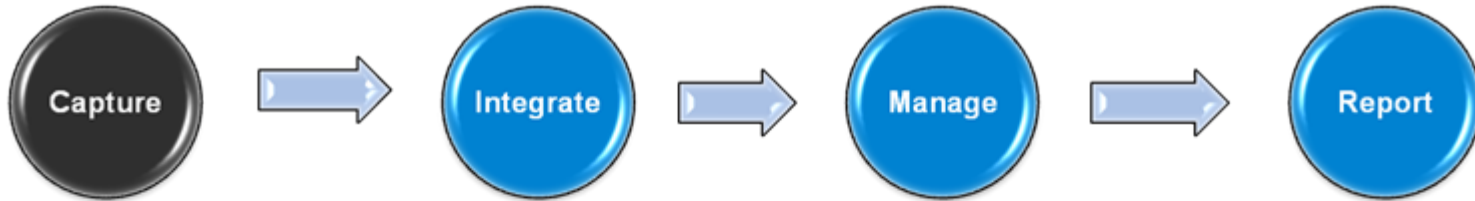


•Capture, **cleanse & augment data** collected from SFA, ERP, T&E, 3rd Party, Grants systems

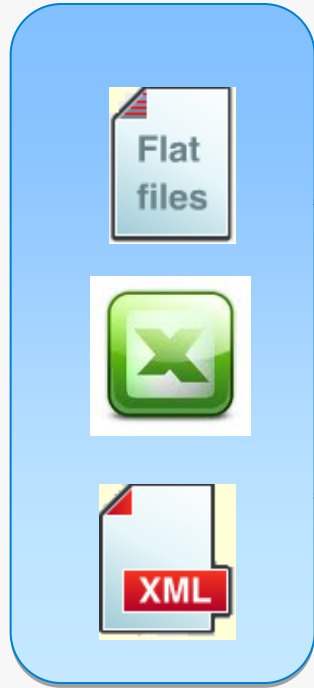
- Strive to use Customer Master Reference Data
- Flexibility for Vendors to Load Data via System Interfaces, Excel File Uploads or Data Entry Screens
- Vendor Access to the System in a secure segregated manner



Aggregate Spend Solution – Capture



Data Interfaces



Aggregate Spend System

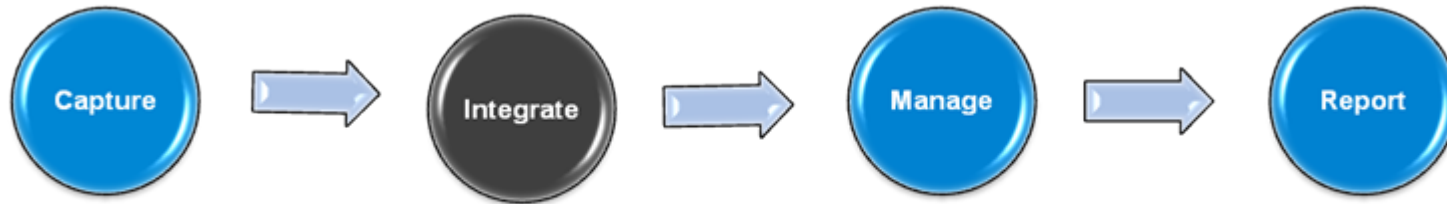
Expense Spreadsheets



Manual Entry

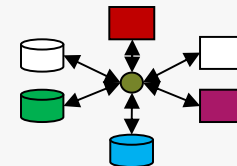


Aggregate Spend Solution – Integration

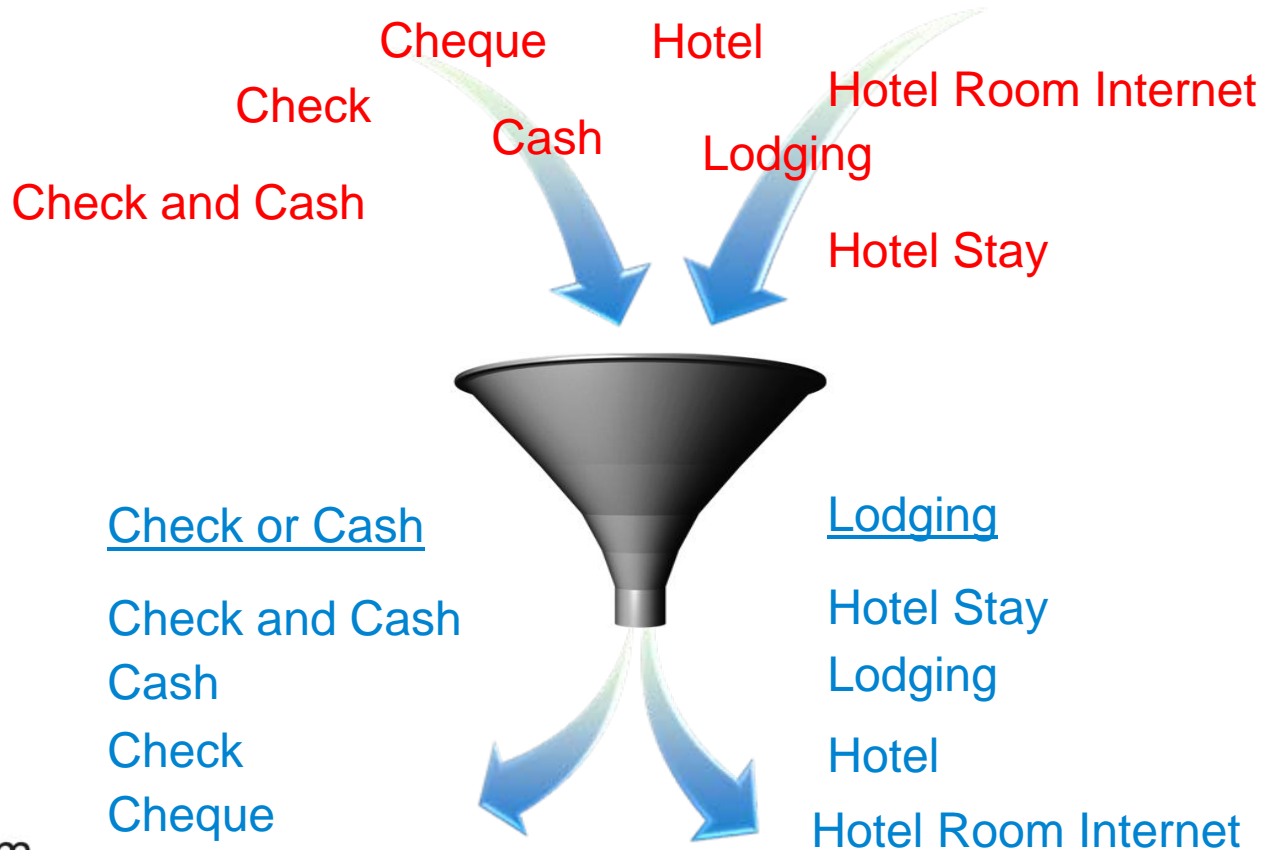
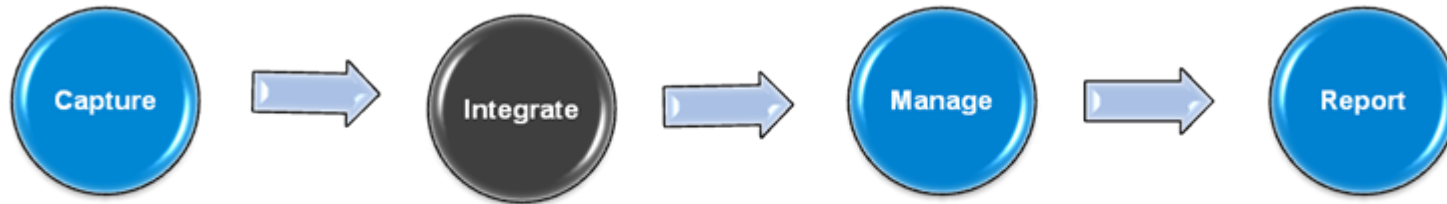


- Establish an **Identity** for the HCP across systems
- Manage & Resolve **Exceptions**
- Maintain **Relationships**

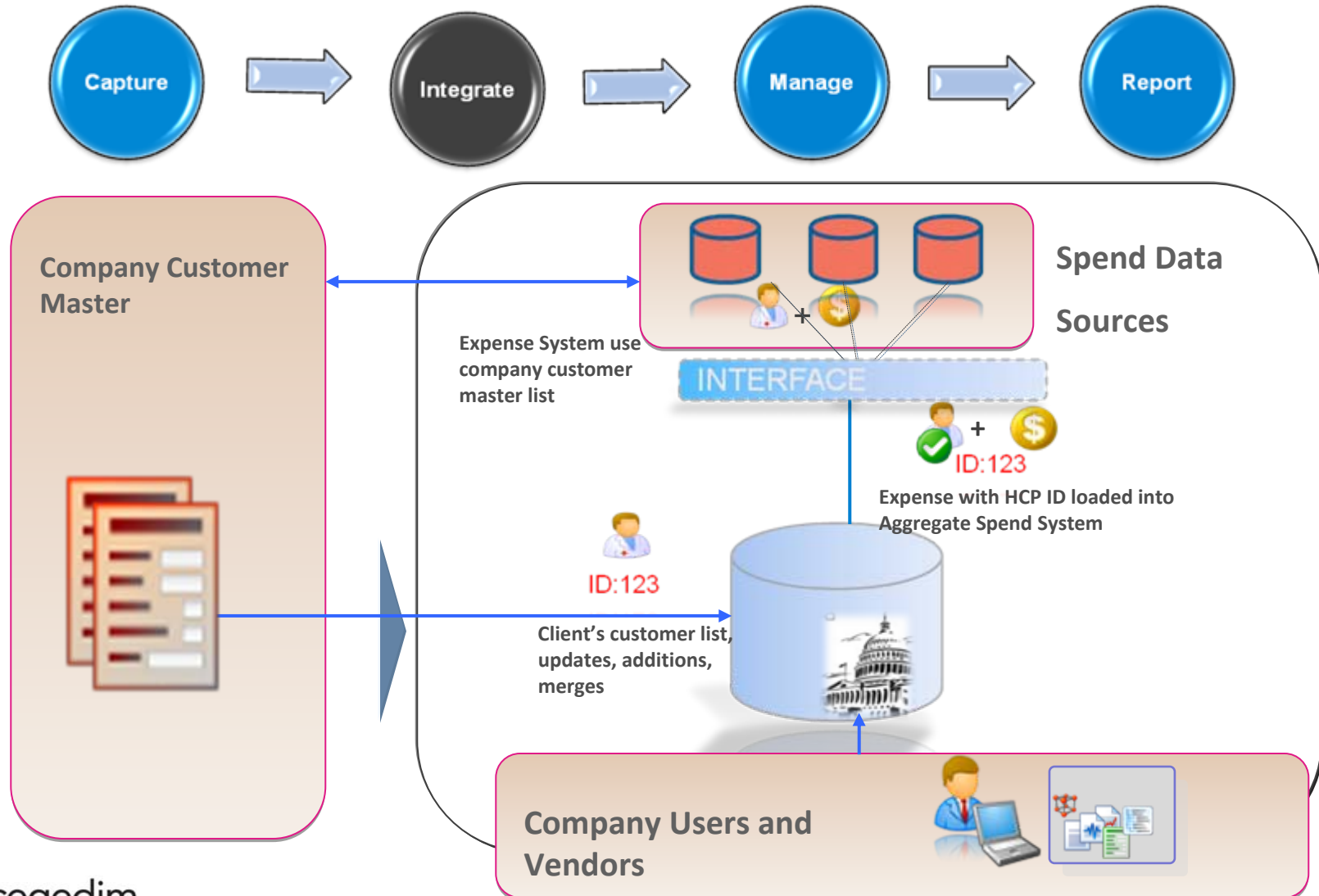
- Use for Reference the Customer Master data
- Resolve Spend data by Matching against the Customer Master
- Monitor Vendor Spend Feeds



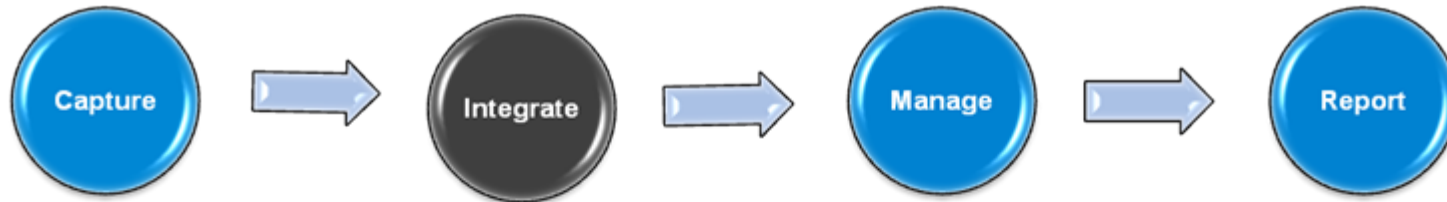
Aggregate Spend Solution – Integration



Aggregate Spend Solution - Customer Master



Aggregate Spend Solution – Integration

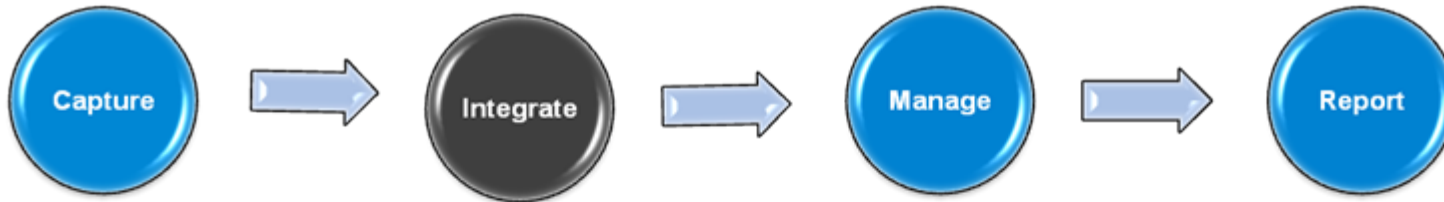


Source(ID)	First	Last	Deg	Specialty	Phone	Address	SLN	Email
SFA (1+34AJ)	William-	SMith		Unknown	#555 1234	123 main st, Mt arlington, NJ	98765	smith@diagnostoc.com
3rd Party (1929392)	W. (Bill)	SMITH	M.D.	0021	9735551232	12 Ronald Ave, NJ 07921		
SLN Vendor (10002930)	W	Smith	MD	IM		12 Ronald Ave, NJ 07921	25MA098765	
Web Reg (00110_MD)	Bill	smith	001		9085551234			Will.Smith59@hotmail.com

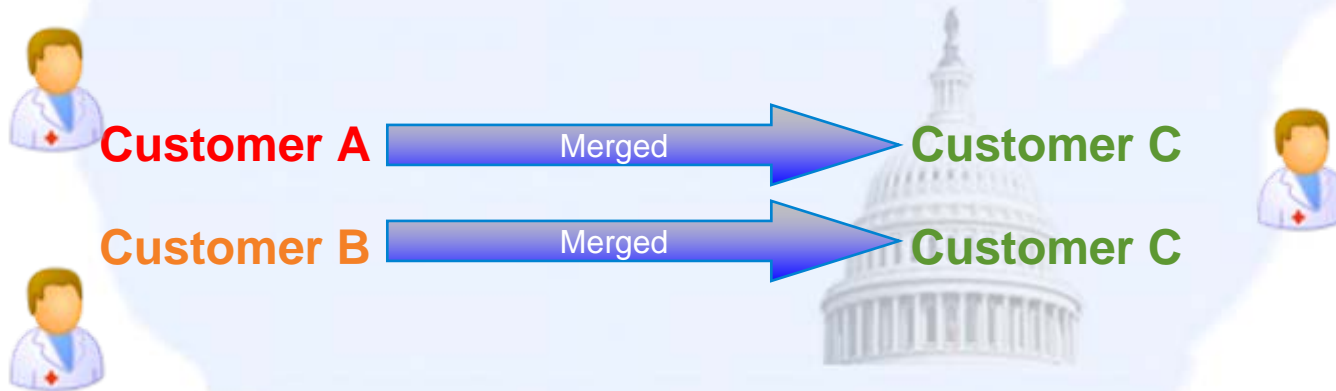
Generate Single View

Source	First	Last	Deg	Specialty	Phone	Address	SLN	Email	Audit
CCV = 23458 - Xref - 1+34AJ 1929392 10002930 00110_MD	William	Smith	MD	Internal Medicine	(908) 555-1234	123 North Main St, Mt Arlington NJ, 07856 12 Ronald Ave, Bedminster NJ. 07921	25MA098765	smith@diagnostoc.com Will.Smith59@hotmail.co m	C_DT: 1/1/10 C_ID: jpeters L_UDT: 6/7/10 L_UID: jjohn Version: 6

Aggregate Spend Solution – Integration



→ **Customer Merges Must be Handled As Part of On-Going Customer Management**





Aggregate Spend Solution – Integration



US Medical Affairs



Hospital Foundation
Grant for Clinical Research
\$ 50,000



Technical Assessment of publication
£ 3,800

UK

Medical Affairs



Invited to Medical Congress in BCL
€1.750

Marketing Oncology



Speaker fee at the Intl Congress in Dublin
€5.000



Berlin Hospital
Clinical trial investigator
€14.790



Medical Affairs

\$75,090



Representative

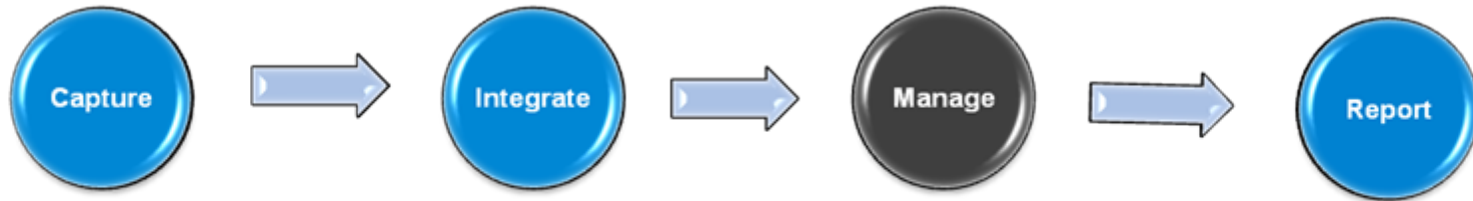
Lunch provided
Education Meeting
\$ 55

MSL

Receive the full Medical Encyclopedia
\$ 750



Aggregate Spend Solution – Management

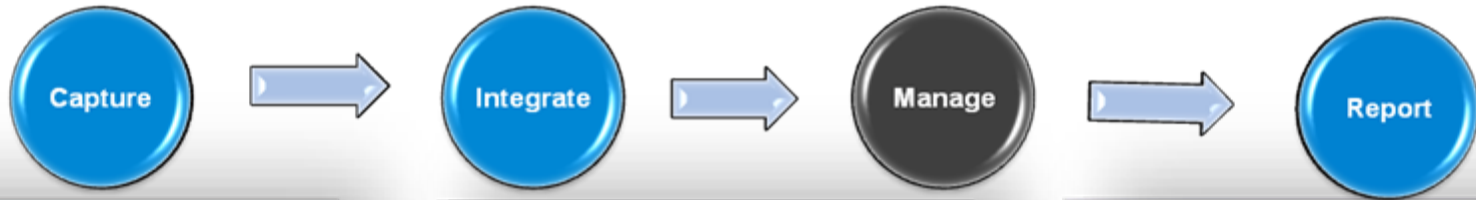


- **Set & Monitor thresholds** using Alerts
- **Manage Report Templates**
- **View, Monitor, and Edit Spend data**
- **Configure and manage rules per latest regulations**



- Threshold Violation Alerts
- Flexibility to handle State Report Format Changes
- Flexibility on Data Mapping and Aggregation based on your Company's Interpretation
- System Audit Trailing to Track Changes by Users

Aggregate Spend Solution – Management



Anti Bribery Provisions

Prohibits bribery of foreign government or political officials for the purpose of obtaining or retaining business or securing any improper business advantage

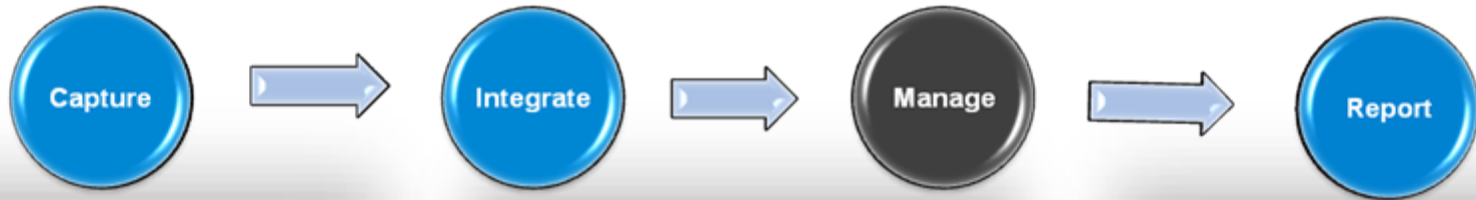
FCPA

Requirements

Books & Records Provisions

Requires SEC-registered or reporting issuers to make and maintain accurate books and records and to implement adequate internal accounting controls

Aggregate Spend Solution – Management



Anti Bribery Provisions

Capability in Solution

- *Store relationships between HCP and Organization such as hospitals*
- *Alerts to detect spend on HCPs with specific relationships with organizations (employed at government hospital)*

FCPA

Requirements

Books & Records Provisions

Capability in Solution

- *Store the requisition # and purchase # for spend*
- *Ability to view a scanned image of the documents*

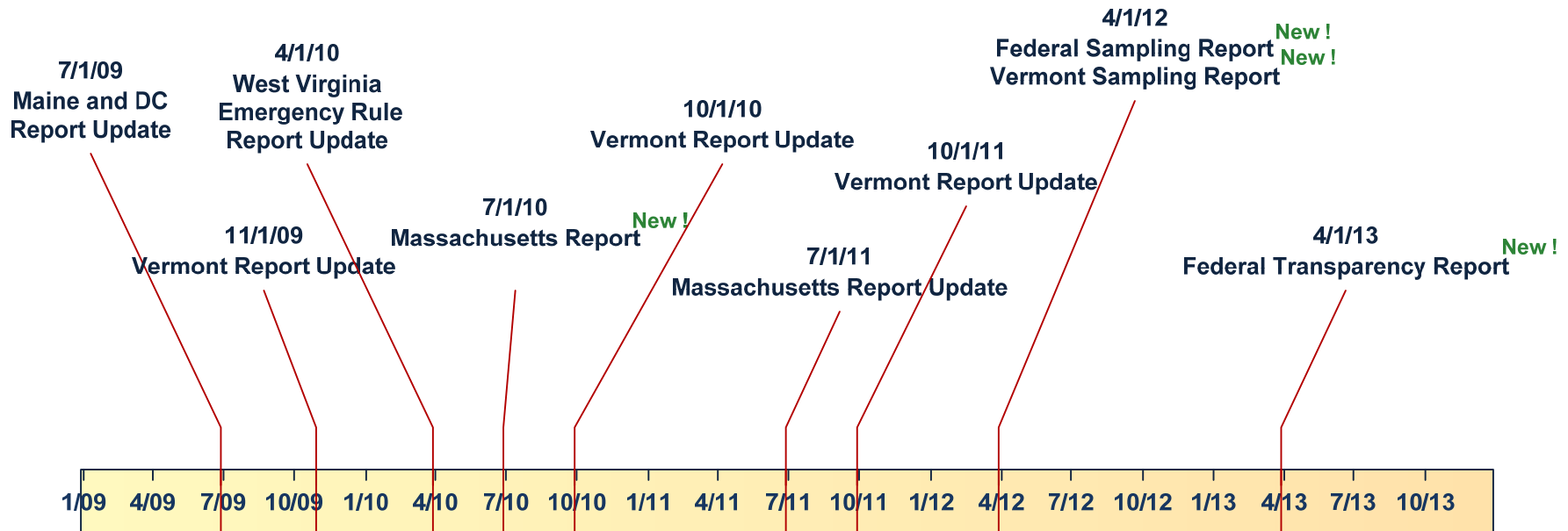
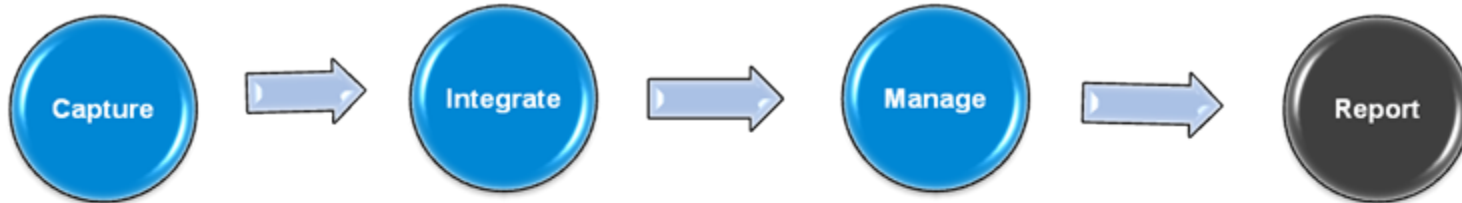
Aggregate Spend Solution – Spend Reporting



- Submit reports in **State** mandated **formats**
 - **Configure** Spend Types using your **terminology**
 - **Maintain** an archive of **submitted reports & templates**
-
- Easily generate State Reports
 - Be Prepared for Federal Reporting (Sunshine Act)
 - Generate Adhoc Reports
 - Be prepared for Trend toward Reporting against Company Policies



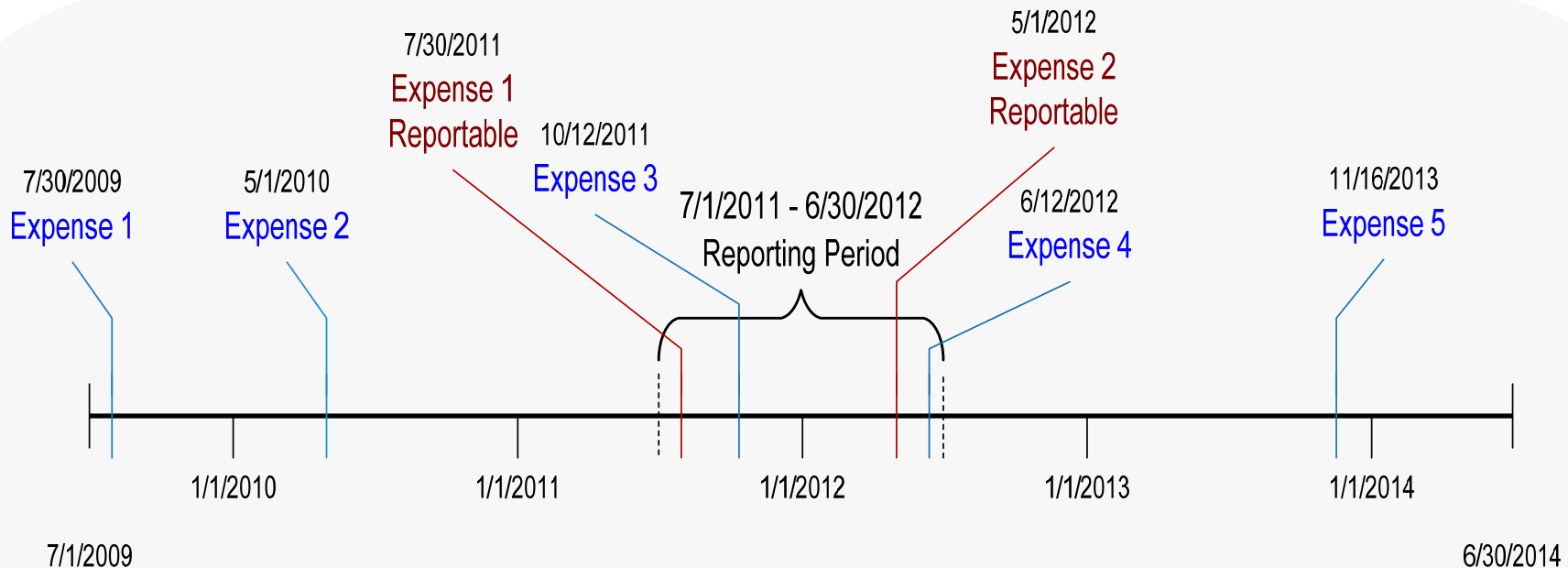
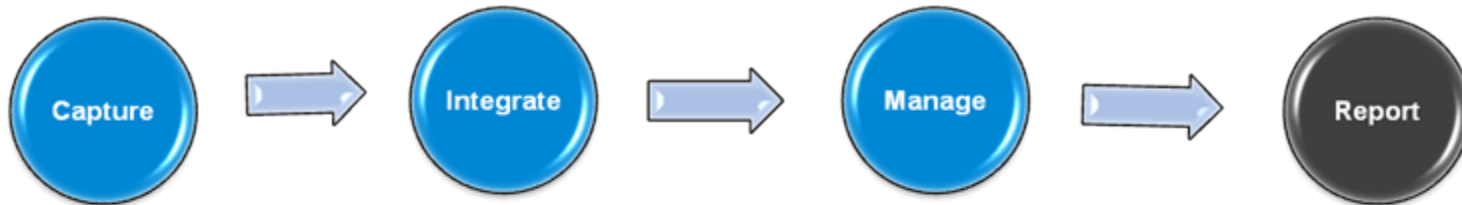
Aggregate Spend Solution – Management



Jan 2009

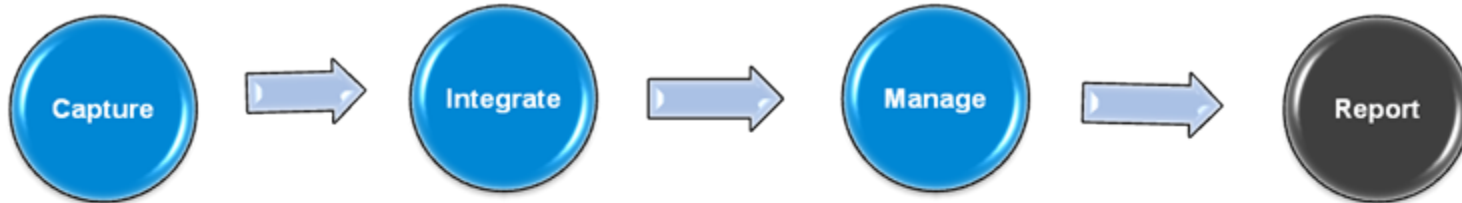
Dec 2013

Aggregate Spend Solution – Spend Reporting



For Vermont, expenses subject to two year delayed reporting on products not approved or cleared by FDA; expense will be reportable two years after the expense is incurred.

Aggregate Spend Solution – Spend Reporting



Search Constraints

Customer Name:

Nature of Payment:

Value of Payment From:

Value of Payment To:

National Provider Identifier:

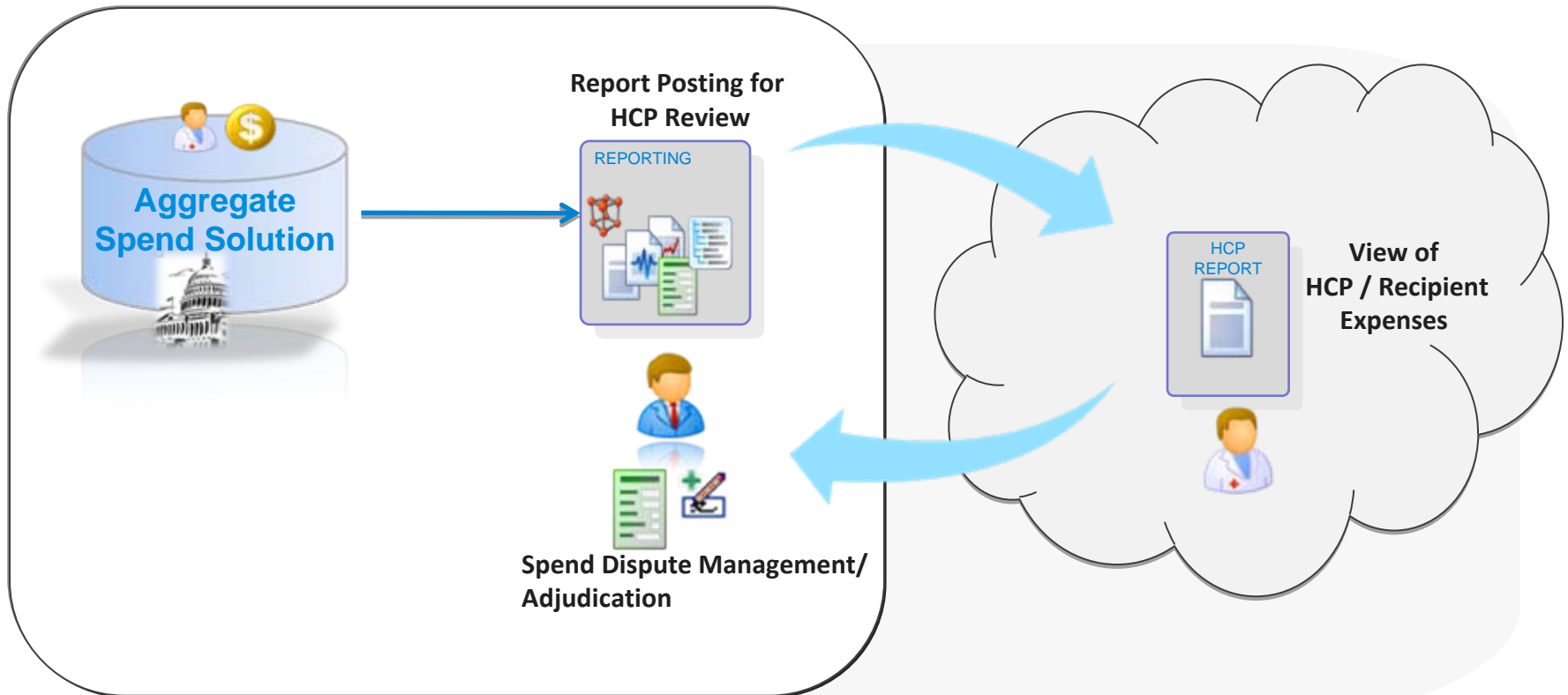
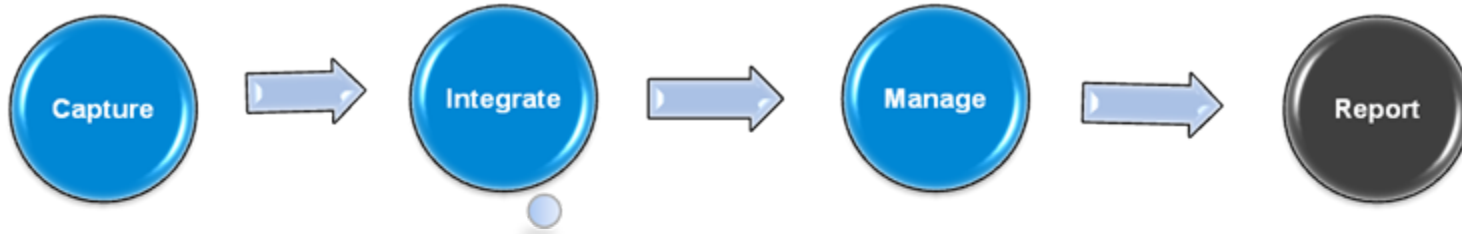
Purpose of Payment:

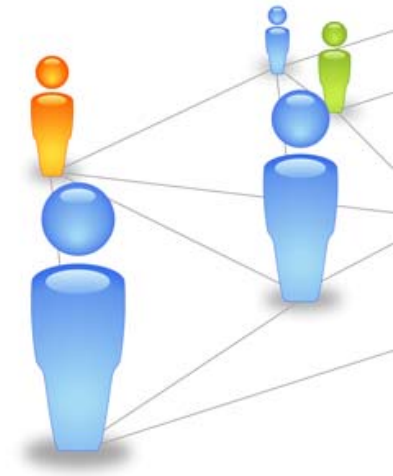
[Clear](#) [Search](#)

Demo spend report 1

Customer Name	Address	Specialty	National Provider Identifier	Value of Payment	Transfer Date	Nature of Payment	Purpose of Payment	Product Name	Travel Destination
MICHAEL SMITH	12401 WASHINGTON BLVD 14702-0000	FM	152898	\$100.00	10/12/2010	Cash	Education	DENCART	
MICHAEL SMITH	A205 CLINICAL CTR 12599-0000	FM	152898	\$300.00	10/13/2010	Cash	Education	DENCART	
JOHN SMITH	DELORENZO TRI CARE CLINIC 14595-1643	FM	144699	\$100.00	10/11/2010	Cash	Education	DENCART	
JOHN SMITH	DELORENZO TRI CARE CLINIC 14595-1643	FM	144699	\$100.00	10/12/2010	Cash	Education	CEGECAL	
JOHN SMITH	DELORENZO TRI CARE CLINIC 14595-1643	FM	144699	\$200.00	10/11/2010	Other	Consulting Fees	DENDARZ	
JOHN JONES	2150 PENNSYLVANIA AVE NW 14858-1848	FM	129189	\$100.00	10/11/2010	Cash	Education	DENDPED	
JOHN JONES	2150 PENNSYLVANIA AVE NW 14858-1848	FM	129189	\$200.00	10/11/2010	Other	Consulting Fees	DENDARZ	
JOHN JONES	2150 PENNSYLVANIA AVE NW 14858-1848	FM	129189	\$500.00	10/14/2010	Travel	Meeting	DENCART	12401 WASHINGTON BLVD 147020-00...

Aggregate Spend Solution – Spend Reporting





GLOBAL TRANSPARENCY

International Scrutiny on Spend Data











Foreign Corrupt Practices Act

UK Anti-Bribery Act

U.S. Corporations / Securities listed in the U.S	Any corporate conducting business in the U.K.
Corrupt activity or intent	Receipt / payment of bribes
Directly or indirectly	Directly or indirectly
Public officials	Public and private sectors
Extra territorial reach	Extra territorial reach / no need to any nexus between the offending conduct and the U.K.
Civil or Criminal (\$2M-\$25M / 5 to 20 years)	Civil or Criminal (10 years / unlimited fines)

Global Transparency- Code of Conduct Examples



	<p>Items must not be offered for the personal benefit of healthcare practitioners or staff Items must be inexpensive – relevant to the recipient’s profession and £6 limit Companies must make publicly available financial support for public/patient groups and donations / grants to support healthcare and research</p>	<p>£6</p>
	<p>Gifts must be “inexpensive” The occasion for such a work lunch/dinner must be documented The companies must publish the granting of donations or other unilateral monetary or benefits with a value of more than € 10,000 per benefit recipient/year. The member companies must give details of donations made from the 1 January the 31 December.</p>	<p>Max. 10K€</p>
	<p>inexpensive gifts related to the practice of medicine or pharmacy. Gifts will be considered to be inexpensive when their cost does not exceed 30 Euros.</p>	<p>30 €</p>
	<p>Gifts can not exceed 100 PLN as long as related to medical practice.</p>	<p>100 PLN</p>
	<p>Companies can only put up to 50% of the cost of doctor’s travel and accommodations at conferences</p>	
	<p>Gifts can not exceed € 20 as long as related to medical practice Can provide scientific publications as long as they don’t exceed € 500 per year per physician</p>	<p>20 € / max. 500 €</p>
	<p>Gift inexpensive and relevant to recipient’s practice or employment Small gift shall not exceed 20 YTL; authorized gifts (listed) for use exclusively in medical practice shall not exceed 200 YTL</p>	<p>20 YTL / 200 YTL</p>
	<p>Gift shall be less than 200 CZK Medical literature shall be less than 1,500 CZK Total annual spend shall not exceed 1,500 CZK</p>	<p>200 CZK / max. 1,500 CZK</p>

Company Expenditure Monitoring in US & Europe

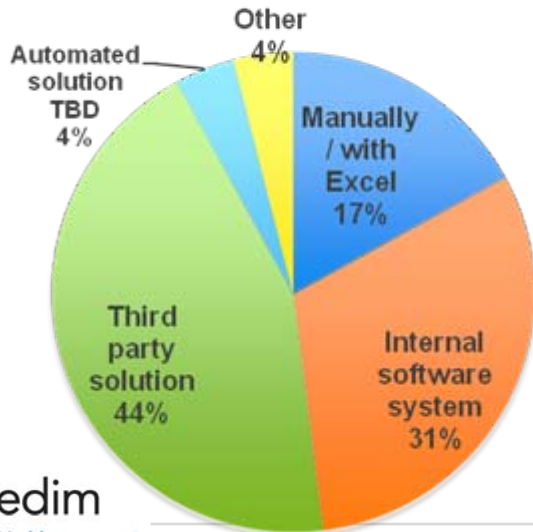


U.S.

How companies report today?

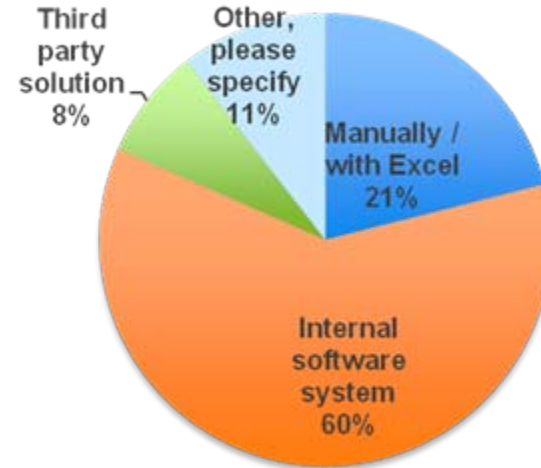


How companies will report as more legislation passes ?

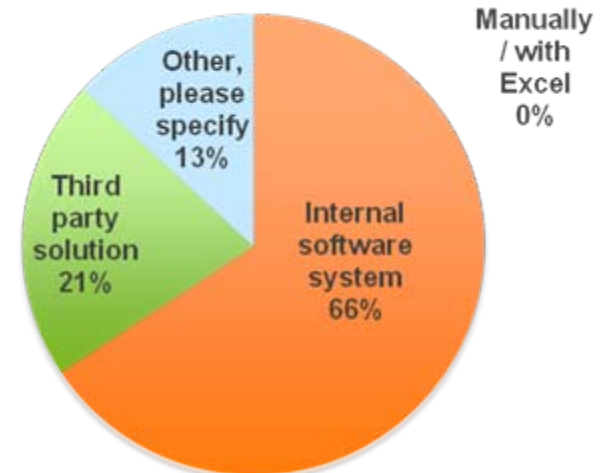


Europe

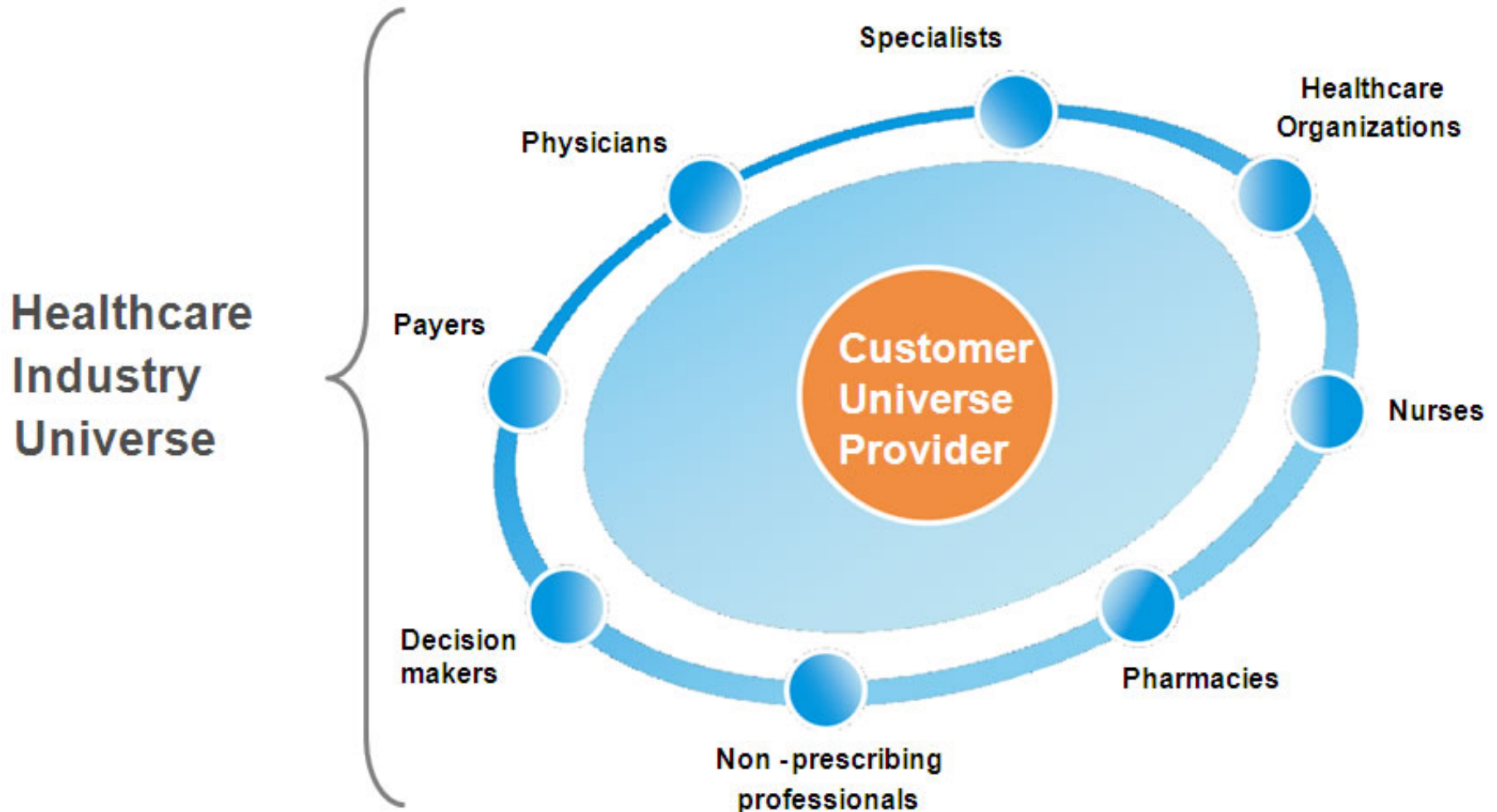
How companies monitor expenditure today?



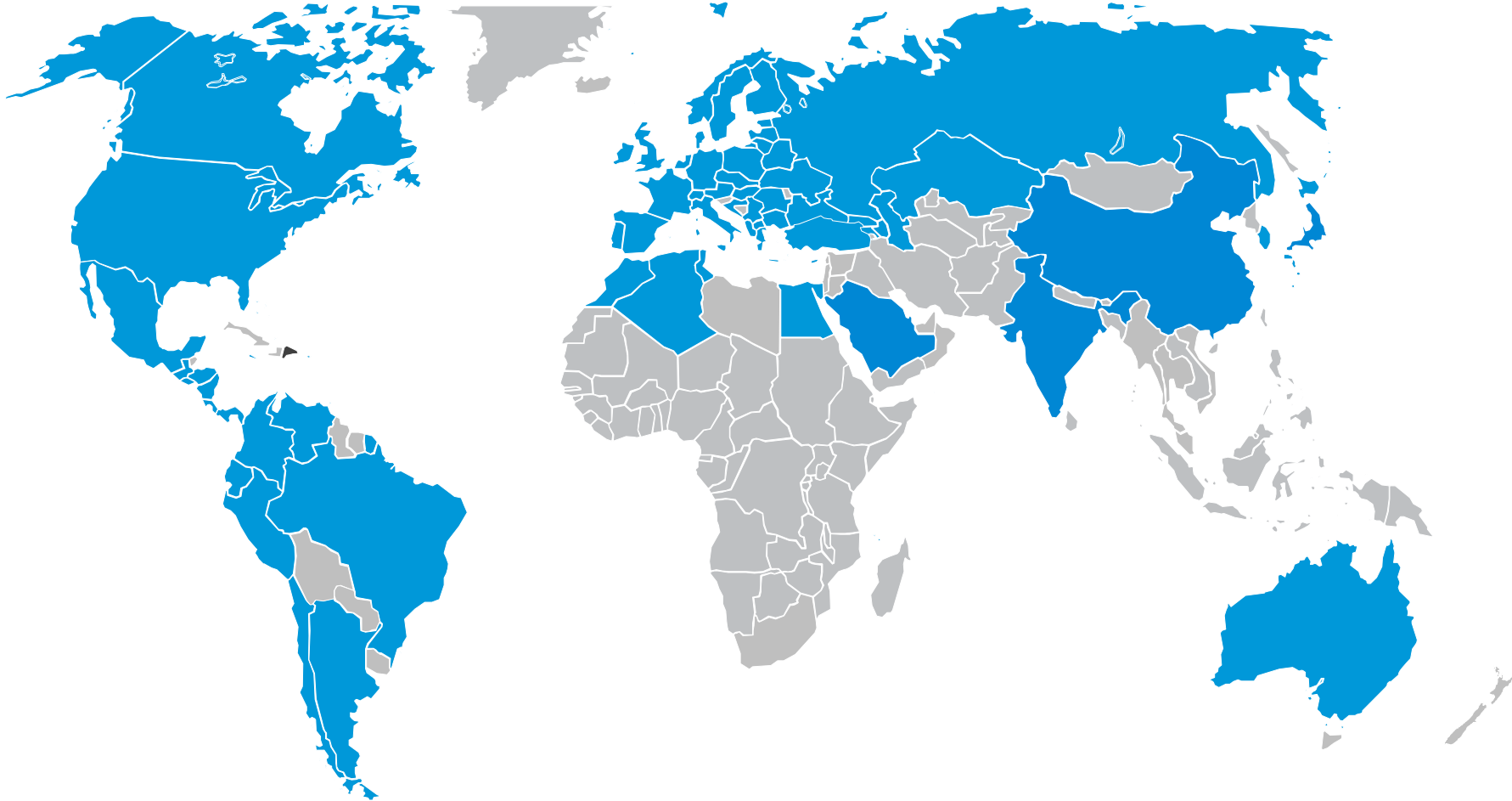
And how will you satisfy spend transparency requirements tomorrow ?



Global Transparency- Comprehensive Customer Universe



Global Transparency Coverage



Supported by HCP coverage on a global basis



Thank you...

Email: compliance@cegedim.com
www.cegedim.com/compliance