Global Transparency – Focus on HCP/O Engagement Process

CBI - 4th Annual Global Transparency Reporting Congress

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About The Speakers

David Eiben
Director, IS Business Partnering

David has been with Boehringer Ingelheim Pharmaceuticals, Inc. (BIPI) for over fourteen years in several roles, providing internal consulting and program management to Marketing, Research & Development, Commercial Operations, and Compliance across a wide range of regional and global programs.

Currently, David supports BI's Global Legal & Compliance organization with a focus on global end-to-end HCP Engagement management. David led the global team responsible for developing the proposal to create the global 'Clearing House' which manages global cross-border spend pre-approvals; this effort resulted not only in the creation of a new corporate function but also was a precursor to implementation of our cross-border spend management system.

Before joining BI, David worked in the SAP vertical of PwC's Management Consulting practice. Early in his career, David also worked in Business Development for an industrial division of Emerson Electric. He has a MBA from the Tepper School of Business at Carnegie Mellon University and a BS in Welding Engineering from The Ohio State University.

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About The Speakers

Marc Eigner
Partner, Co-Founder, Polaris Solutions

Marc heads Polaris' technology practice, and is a co-founder of Polaris Solutions. Marc is considered the leading experts in Pharmaceutical compliance technology, including HCP/HCO spend automation and aggregate spend systems. Marc has spoken at many conferences on these topics. Marc has helped grow Polaris' technology practice from a small team to the largest Pharmaceutical compliance focused technology groups in the industry.

Marc has personally supported over 60 pharmaceutical companies with their processes and systems for supporting HCP/HCO spend and aggregation.

Before joining Polaris, Marc worked in Accenture's technology practice, specializing in ERP implementations and Web technology. Early in his career, Marc worked for IBM. He has an MBA in IT Management, an MS in Computer and Systems Engineering, and a BS in Computer Engineering from Rensselaer Polytechnic Institute.

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Session Overview

To meet transparency and reporting obligations outside of the U.S., as well as address FCPA concerns, companies must develop processes to collect HCP/O spend data on a global scale.

These data collection requirements can be incorporated in a broader global HCP/O engagement process, however various challenges must be overcome to streamline this process across affiliates.

In this session, discuss best practices in deploying a global process and system within a process area that is notoriously hard to standardize across geographies.

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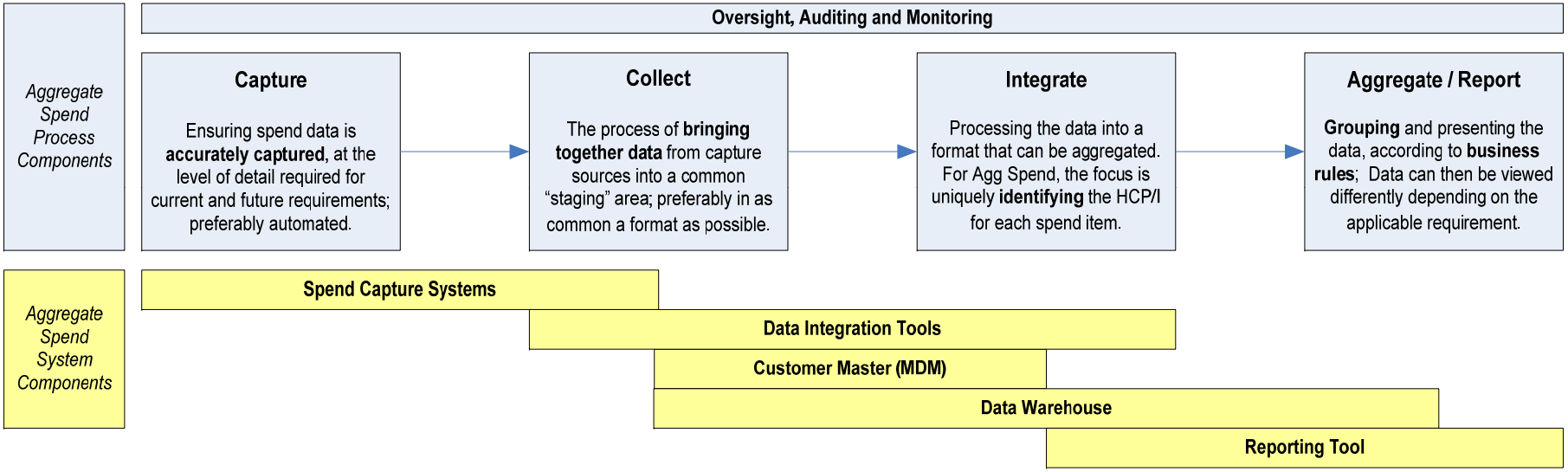
This Again!



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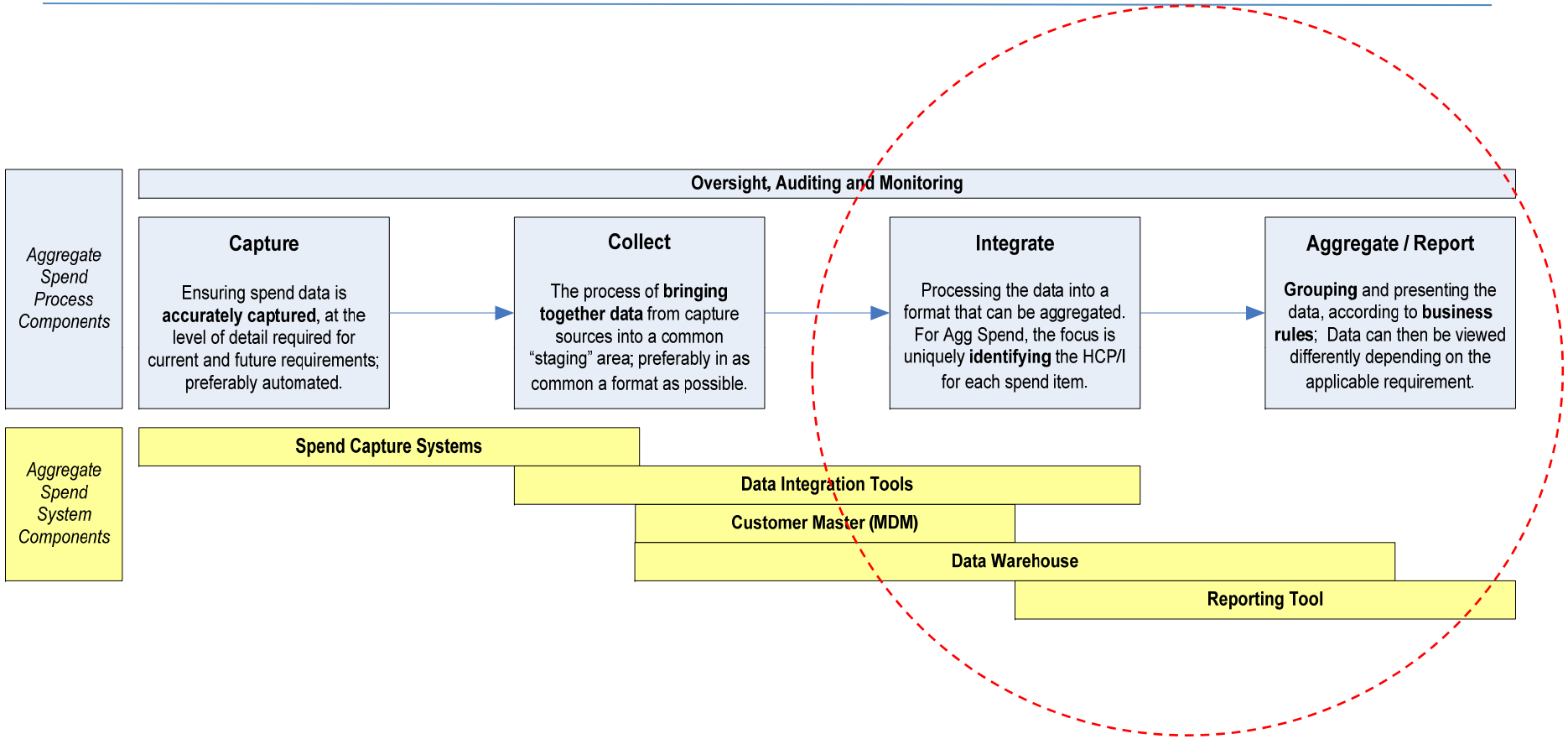
Aggregating and Reporting Initial Focus of Most Companies – Ensure Something is in Place for Sunshine / EFPIA



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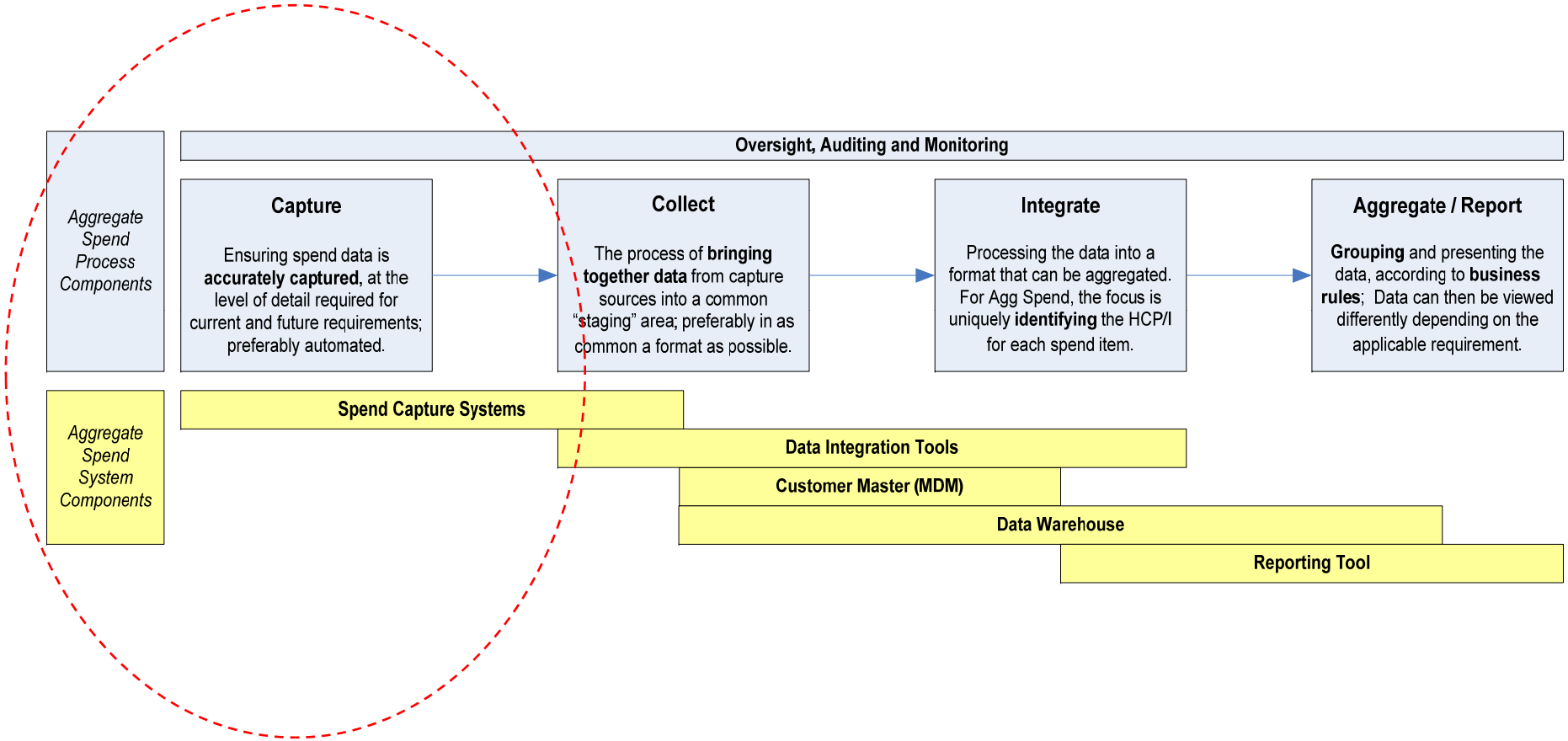
Today's Key Message: Spend Capture Is the Most Overlooked Section, Especially in Regions Without Mature HCP/O Engagement Processes



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Session Overview

As companies struggle with global transparency, many focus entirely on aggregation processes and systems; or, taking a Sunshine Act system and globalizing.

However, the challenge begins long before HCP spend is aggregated or a report is created. This is especially true in regions where HCP spend capture processes and systems are not mature.

In this session, the criticality, to transparency, of the entire HCP engagement process is discussed.

Topics:

- Process considerations for a global HCP engagement process
- Technical considerations to a global HCP engagement process
- Key best practices

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Audience Checkpoint

- Has your company started looking at the global HCP engagement process?
- Do you have a consistent process for engaging HCPs across the globe?
- What are your biggest concerns with the global HCP engagement process?

Please discuss in small groups for 5 minutes.

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Process Challenges

1. Global buy-in (convincing leadership that HCP engagements falls within transparency especially within regions that are not under existing or pending transparency rules)

2. Terminology / Taxonomy (definitions for funding request types)

3. Identification of Owner(s) of Spend Overlapping Regions (Cross-border, global groups, etc.)

4. HCP Nomination and Needs Assessment Processes

5. Due Diligence / Background Checks

   - Third party risk assessments

   - External background screening services

   - Integration with ABAC programs

6. Fair Market Value (FMV)

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Three FMV Calculation Approaches Used To Address Potential Data Limitations For Individual Countries Or HCP Types

Salary Data Calculation

- Salary data collected for specific countries and HCPs specialties
- Hourly FMV rates calculated including adjustments for
  - Hours worked
  - Overtime pay / Consulting premium
  - Non-cash employment costs

Survey Of Industry Payments

- Survey conducted of current HCP speakers and consultants
- Respondents report fees received from Industry by type of service
- FMV rates and Fees calculated
- Only blinded results reported

Cross-Border Employment Indexation

- Labor market index developed from global compensation surveys
  - Average salary calculated for professional employees
  - Ratio of average salaries used as labor market index
- FMV rates calculated using FMV in another country multiplied by applicable index value

FMV Hourly Rates

Based on available data

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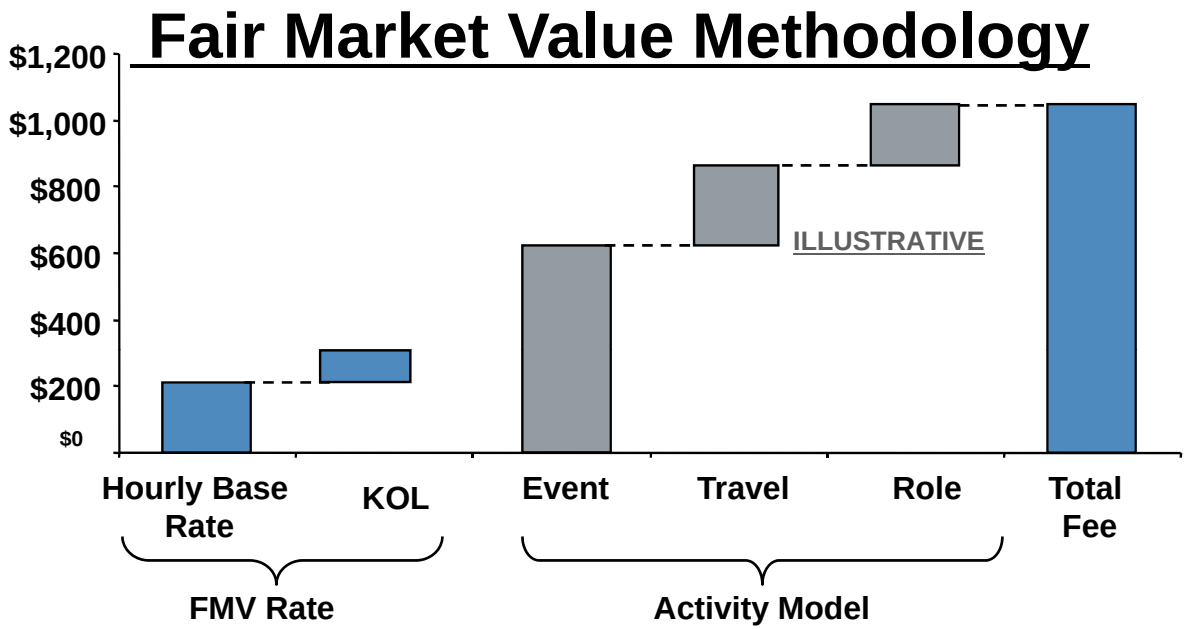
FMV Fees & Standard Fee Schedules Developed From Hourly Rates And Evaluation Of The Work Requirements



Developing Base Rates

- Base rates developed from multiple data sources (Salary Data, Industry surveys, Labor cost indices)
- KOL premiums calculated based on compensation levels for expertise

Evaluating Work Requirements

- Standard fee schedules built from activity models for major program types
- Activity models developed through structured interviews & Polaris experience
- Most significant activity components: event time, travel time, prep-time or consulting role (e.g. Chair vs. Participant)

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FMV Rates & Fee Schedules Created From Three Phased Project Plan Providing For Company Review And Validation

Phase I Data Collection

- **Interviews of business team in each local market**
  - Identify current practices, common activities and requirements, available data sources
- **Survey Company HCPs in each local market**
  - Draft and review survey
  - Translate if necessary
  - Collect email addresses
  - Execute survey
- **Local market data collections**
  - Identify available data
  - Identify regulatory issues
  - Identify compensation practices

Phase II FMV Analysis

- **Prepare hourly FMV rates in each country for target specialties**
  - Analyze HCP survey and calculate hourly rates
  - Calculate hourly rates from available local country data sources
  - Calculation of hourly rates from cross-border indexation
  - Synthesis of rate recommendations
- **Draft fee schedules for each country**
  - Development of activity models in each country
  - Identify fee structure components

Phase III Recommendations

- **Review and validate FMV rates and fee schedules with Company core team**
  - Teleconferences or meetings
- **Discuss implementation recommendations, e.g.,**
  - Fixed fee contracting
  - Fee discounting
  - Rate updating
  - Re-alignment strategies if required
- **Document final recommendations**
  - All materials provided in physical or electronic format

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Technology Considerations

- Some components may be global, such as ERP, CTMS, etc.
- Some components will be local to each country, or non-existent (T&E, grants, IIT, etc.)
- Direct payments to HCPs tend to be in many systems currently (difficult for migration of legacy data)
- Language & Currency
- MDM / Customer Master
  - Global master?
  - Availability of global enrichment data
  - No real regulatory need for data enrichment globally
  - Concept of Compliance Master
- Integration with Global Transparency, if separate initiative
- Data Privacy

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EU Data Privacy

What is the Rule/Law?

- European data privacy is covered under the European Data Protection Directive 95/46/EC ("DP Directive"), which covers all processing of personal data
- The underlying principle of the DP Directive is: "**All processing of personal data needs to be justified either by law or by consent of the data subject**"
- Similar to Transparency, the Member States have implemented the directive into national laws, which closely resemble the Directive
- New version expected in 2014

Why does this matter for HCP Engagements & Transparency?

- HCP profile data, as well as data relating to Transfers of Value can be considered Personal Data
- Reporting of the data can be considered Processing

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EU Data Privacy (cont.)

What is the impact to the HCP engagement process?

- The Directive dictates that processing of personal data needs to be justified therefore by law (Statutory Justification Basis) or consent
- In most countries, the Transparency Code is not (yet) law – some it may never be, so consent is likely required in at least some member countries (and recommend in all)
- Violation is a big deal – **penalties in the new draft are up to €100M or 5% of global revenue, whichever is greater**

How is consent obtained?

- Consent is required to be: informed, clear, unambiguous and freely given
- Some countries require consent in writing, highlighted (if in a contract) and revocable. Written is generally recommended for many countries
- In order to be considered informed, the data subject must know what is captured, and what will be disclosed

Therefore, it is essential to build data privacy requirements into the HCP engagement process early, especially for indirectly paid recipients.

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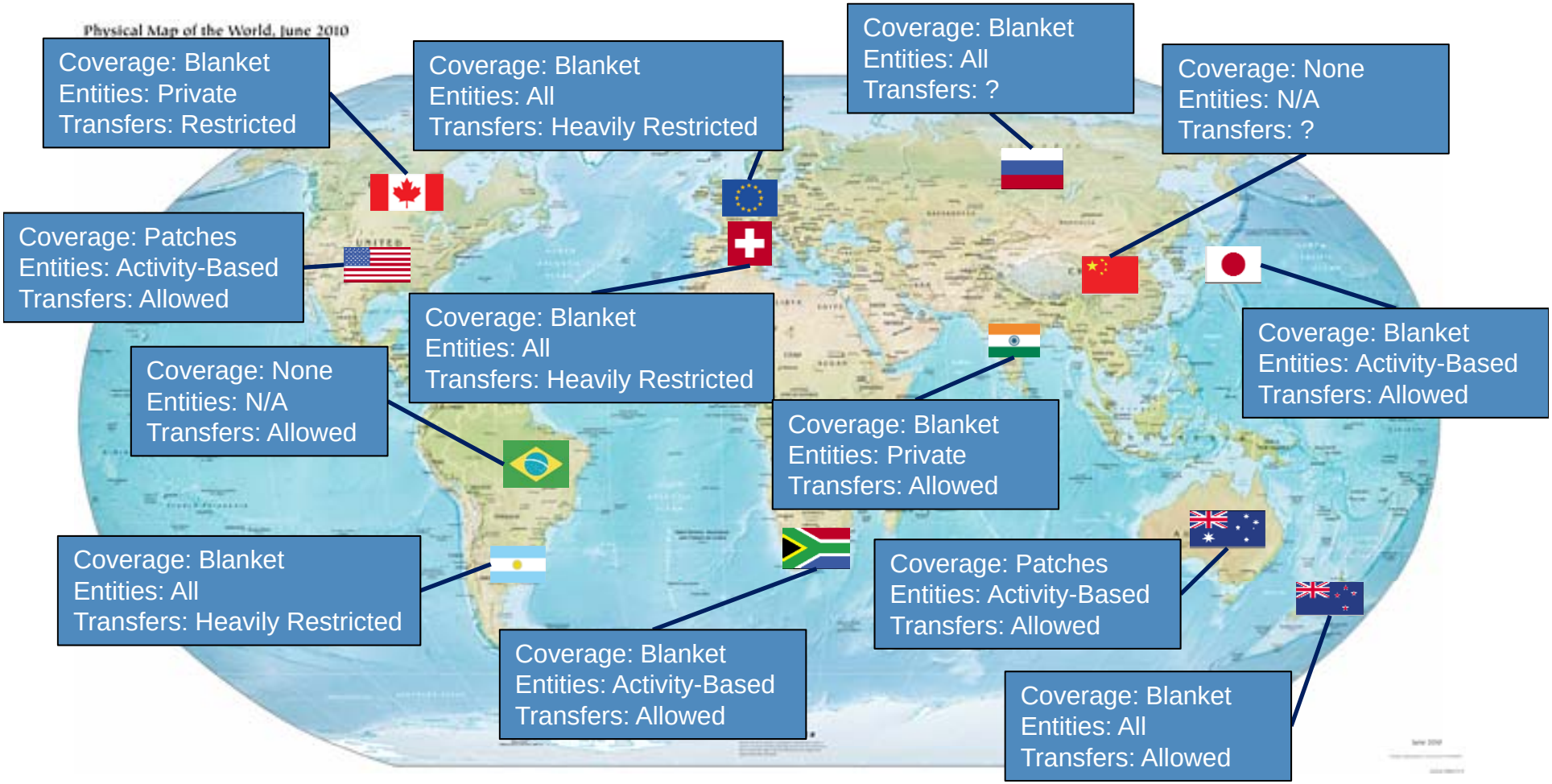
International Data Privacy: Beyond EU



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How to Get Started

1. Establish Guidelines (are you solving Transparency or HCP Spend Automation?)
2. Establish Baseline Collection Requirements
3. Assessment in Each Region / Global Group
4. Prepare Deployment Strategy
5. Get To Work (Systems, Change Management, Training, Etc.)

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Cross Regional Spend Collection

	Planning	Pre-Approval	Contracting	Payment & Reconciliation	Aggregation	Reconciliation	HCP/O Dispute / Validation
Region 1	As Is	☑	As Is	☑	☑	☑	N/A
Region 2	As Is	☑	As Is	As Is	As Is	☑	As Is
Region 3	☑	☑	☑	☑	TBD	☑	TBD
Global Group 1	As Is	☑	As Is	☑	☑	☑	N/A
Global Group 2	As Is	☑	As Is	☑	☑	☑	N/A

Illustrative

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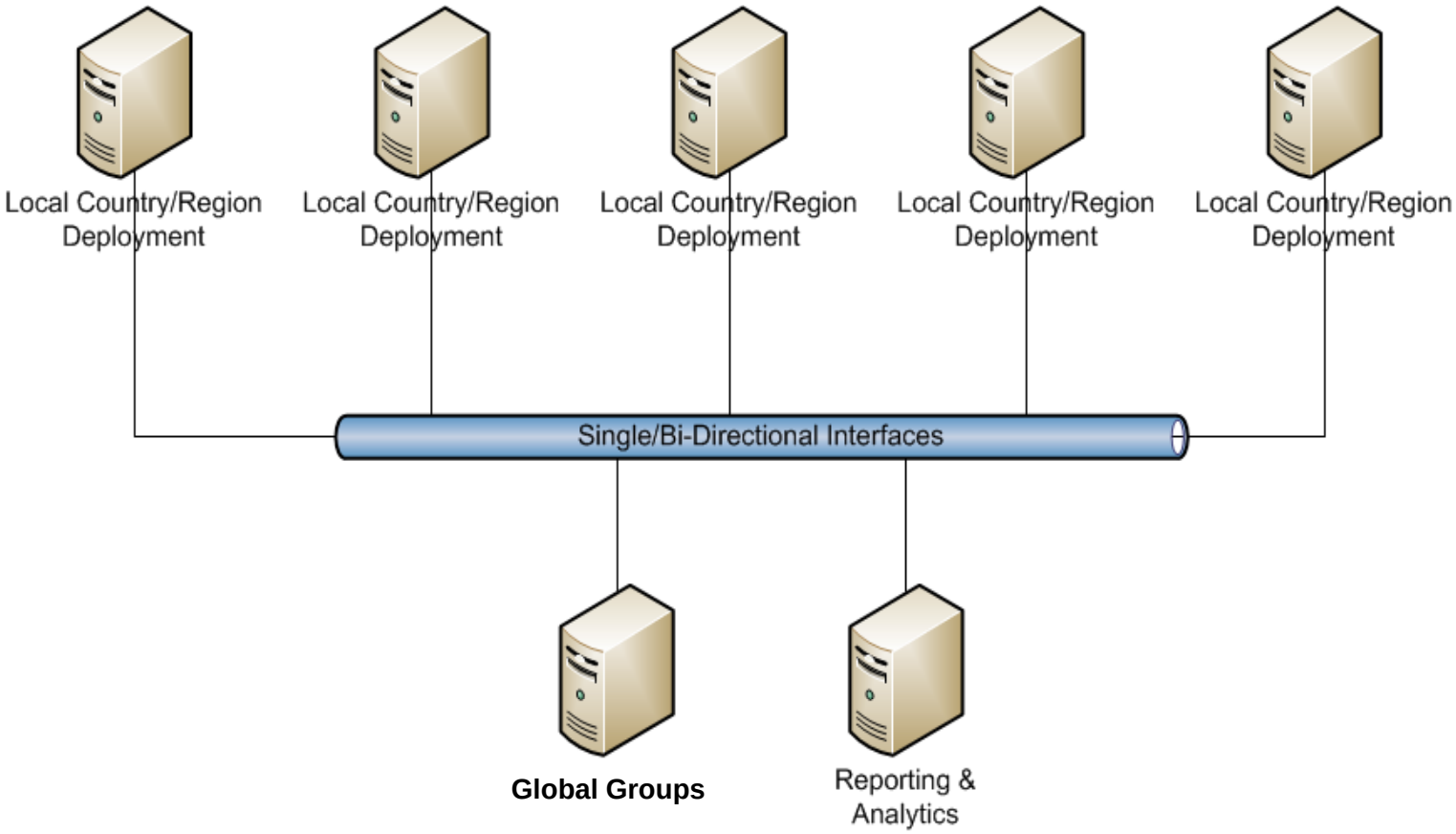
Deployment Strategies



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Deployment Strategies – best practices

- Fixed Duration Pilot
  - Single region, all (or most) transaction types
  - Single transaction type, all (or most) regions
  - Expedited SDLC
  - Key stakeholders engaged
  - Rapid prototyping
- Allows for Proof of Concept
- Requirements Tend to Change During Long Projects Anyway
- Consider Cross-Border and Other Global Groups First
- Consider Foundational Technology (MDM, ERP, CRM, etc.)

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Key Takeaways

- Many companies overlook the HCP Engagement process
- Due to data privacy consent alone (and many other reasons), this is even more critical in Europe
- Consider establishing a Global HCP Engagement team, similar to a Global Transparency team – may even be first
- Consider expanding existing HCP processes, such as FMV
- Build data privacy requirements into systems from day one
- Don’t overcomplicate – tackle HCP engagements and then transparency – outside of the US this is a significant portion of reportable spend
- Don’t underestimate the change management aspects, much more significant than US state laws and Sunshine
- Make sure to coordinate with existing/pending ABAC/FCPA programs

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