HCP Engagement : Best Practices in the Age of Increasing Globalization, Regulation, and Data Privacy

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Today's speakers

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Based out of Amsterdam, Chris van Bronckhorst leads IQVIA Commercial Compliance's business in Europe and the Asia-Pacific regions. Chris began his career as an IT systems developer. From this technical base, he developed over the course of a 22-year career as a manager and consultant in business strategy, program management, business transformation, IT systems implementations and organizational change.

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The Commercial Compliance Landscape

Multiple compliance risk areas

To be managed in collaboration with HCP/Os and life science industry

Anti-bribery / Laundering	Off-label / Disguised Promotion	Conflict of Interest	Data Privacy
Antitrust	Transparency	Local Requirements	Ethics, Image, Reputation

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What are your specific compliance obligations?

You have to manage both industry codes and country-specific requirements

MedTech Europe
- Phased out direct sponsorship for third-party events
- Transparency of educational grants
- Guidelines for interactions with HCPs (e.g. FMV)

AdvaMed : New Code of Ethics
- New code sections for marketing & education programs, communications, and technical support in a clinical setting
- Guidelines for interactions with HCPs (e.g. FMV)

Country Regulations
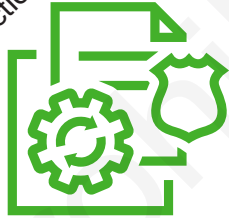- Transparency Reporting Requirements - Portugal, France, Belgium

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But challenges are broader

Compliance risk is only one element

No single, global view of all engagements with HCPs and HCOs

Insufficient compliance controls embedded in the process

Multiple **handover points and manual work**, leading to inefficiencies

Inconsistent **stakeholder experience** (for HCPs/ HCOs)

MedTech companies need a single, global, scalable and efficient view of the customer, with integrated data sources and strategic analytics, delivering a streamlined, end-to-end solution, with built-in compliance controls.

What new needs have arisen in your organization from expanding compliance requirements?

Balancing business demands & compliance obligations:

Companies are looking for **efficiency** to deploy resources to value-added activities

Global solutions, integrated with existing platforms

Obtaining **insight** from the data collected to enable strategic decision making

Cost-effective solutions, configurable and low on support

Faster decision making and turnaround times

Improved **customer relationships** with prescribers through digital engagement

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Key elements for Commercial Compliance within MedTech

Key elements for commercial compliance within MedTech

FMV

Transparency Reporting

Engagement Management

Consent Management

Ensure rates paid to HCP/O's reflect Fair Market Value

Collect, aggregate & report on HCP/O payments or transfers of value

Streamline business processes for HCP/O engagements with embedded compliance and business process controls

Streamline business process for ensure simple, accessible ability for HCPs to provide and revoke consent

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Fair Market Value

Key elements of a successful methodology

Flexible
Ability to pay higher fees for higher degrees of expertise

Consistent
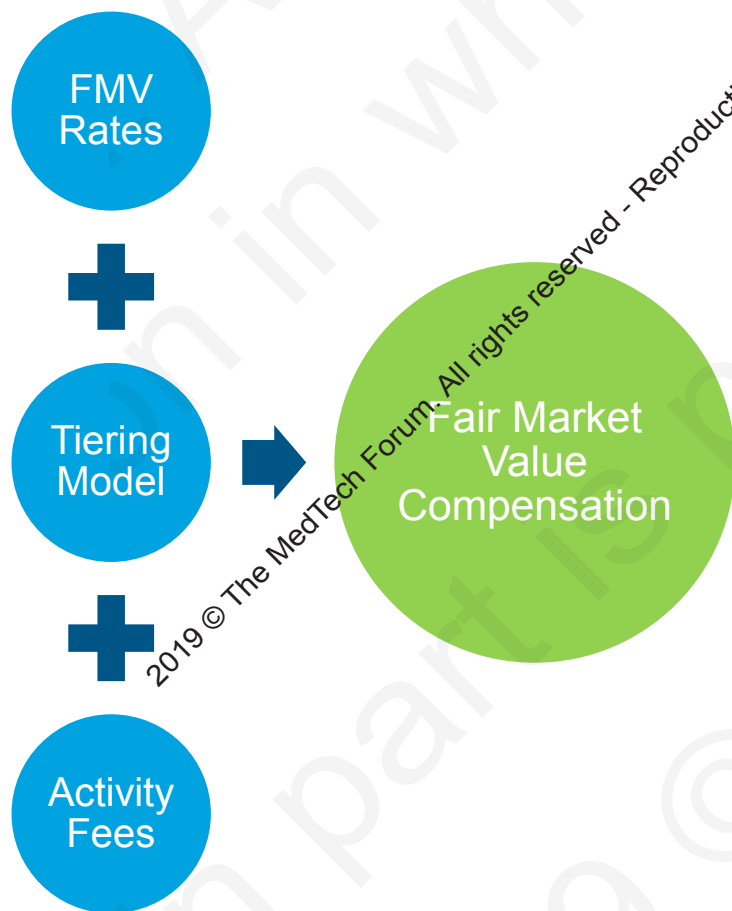Simple model that allow for efficient application

Objective
Specific & measurable criteria for determining tier

Auditable
Maintain auditable records to support rate determination

Three levers of a practical FMV initiative

FMV Rates

+

Tiering Model

+

Activity Fees
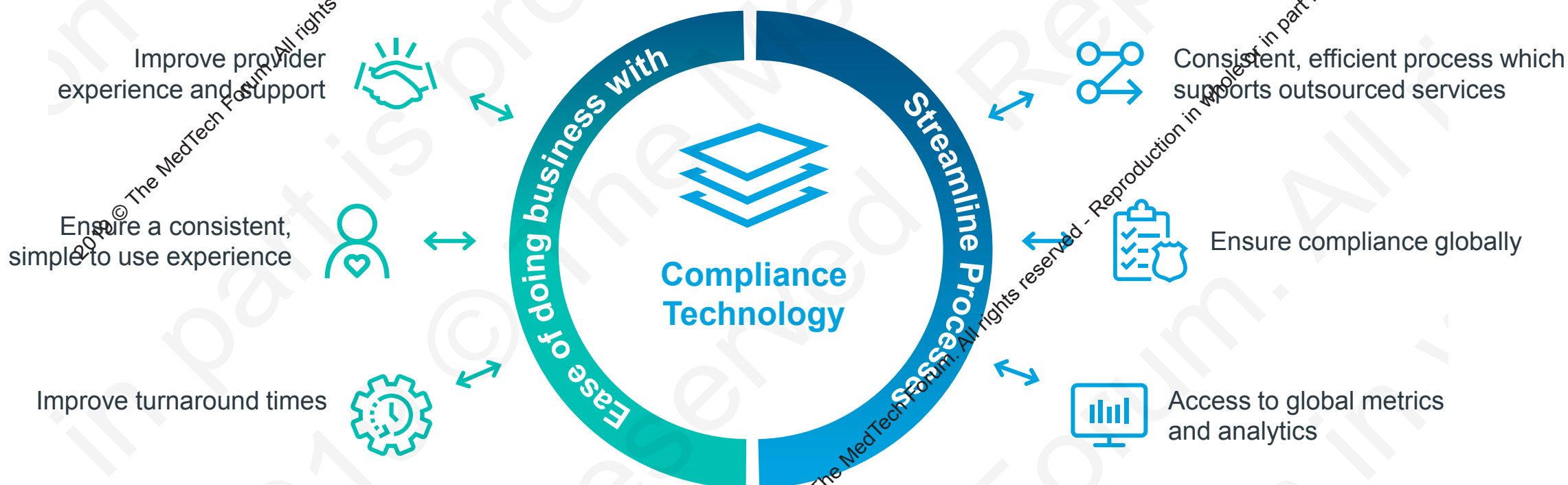
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Fair Market Value Compensation

- **FMV rates should ensure that the value of a physician's time is compensated fairly, without bias based on the value of the service.**

- **While FMV rates based on objective data are a key control in the HCP engagement process they need to be supported by robust tiering models and consistent activity fee practice.**
  - Compensation data used for FMV represents national averages.
    - o Industry does not routinely engage "average" physicians.

- **If you compensate based on tier, without a standard methodology it is difficult to ensure consistency.**
  - If you lack consistency, the control is **not** working.
  - Depending on your rate methodology the overpayment could be 20% - 80% depending on country and specialty.

- **FMV as a risk control is also strengthened if companies pay similar fees for similar activities based on standard service level expectations.**

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Engagement management

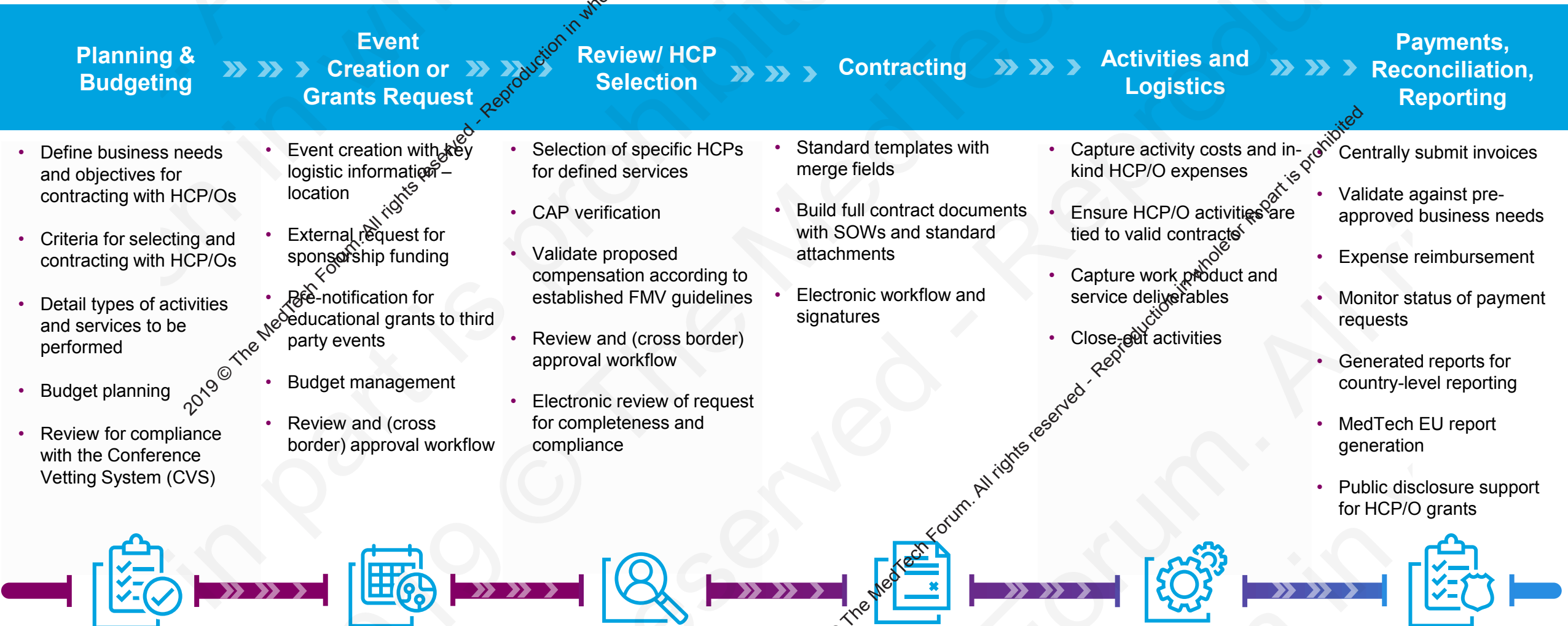*Improves "ease of doing business" while strengthening internal compliance controls*

Increase ease of doing business with HCP/O's	Streamline internal Engage to Pay Processes globally

Improve provider experience and support

Ensure a consistent, simple to use experience

Improve turnaround times

Ease of doing business with

Compliance Technology

Streamline Process

Consistent, efficient process which supports outsourced services

Ensure compliance globally

Access to global metrics and analytics

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End-to-end management for the complete engagement lifecycle

Process automation in HCP/O consulting, sponsorships and transparency reporting readiness

Planning & Budgeting	Event Creation or Grants Request	Review/ HCP Selection	Contracting	Activities and Logistics	Payments, Reconciliation, Reporting
• Define business needs and objectives for contracting with HCP/Os • Criteria for selecting and contracting with HCP/Os • Detail types of activities and services to be performed • Budget planning • Review for compliance with the Conference Vetting System (CVS)	• Event creation with key logistic information – location • External request for sponsorship funding • Pre-notification for educational grants to third party events • Budget management • Review and (cross border) approval workflow	• Selection of specific HCPs for defined services • CAP verification • Validate proposed compensation according to established FMV guidelines • Review and (cross border) approval workflow • Electronic review of request for completeness and compliance	• Standard templates with merge fields • Build full contract documents with SOWs and standard attachments • Electronic workflow and signatures	• Capture activity costs and in-kind HCP/O expenses • Ensure HCP/O activities are tied to valid contracts • Capture work product and service deliverables • Close-out activities	• Centrally submit invoices • Validate against pre-approved business needs • Expense reimbursement • Monitor status of payment requests • Generated reports for country-level reporting • MedTech EU report generation • Public disclosure support for HCP/O grants

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To what extent has your organization successfully operationalized the end-to-end process for HCP/O engagement and reporting?

If yes, how was this accomplished?

Global HCP engagement management

Case Study

BEFORE

- Growing reporting regulations
- Disconnected systems
- High cost of maintenance

AFTER

- Solved compliance requirements
- Single solution for transfers of value
- Increased IT efficiencies

Situation	Solution	Result
• **Regulations and codes** regularly introduced or changed globally	• Deployed a global interaction portal to **manage transfers of value**	• Automated **compliance obligations** and **reduced risk exposure** globally
• No **centralized or standardized** data systems in place	• One portal provided **single sign-on** access to various systems	• Tracked, approved, and reported all **HCP and HCO transfers of value**
• Lack of a **single tracking process** for HCP engagement lifecycle	• **Improved data integrity** with one source of validated master records	• Client now has a system that is: **Efficient, scalable, global** and provides **access to data and analytics**
• **High IT costs** due to system complexity and lack of manageability	• **Distributed relevant data** among customer's operational systems	

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Advanced functionality: data analytics

Using data to improve operational efficiency

Turn knowledge into actionable insights

Reports

Visibility into program activity, success measurement (utilization, caps, etc.) globally

Metrics

Turnaround times, provider satisfaction, spend metrics, historical measurement, most frequently used providers

Alerts

Alerts to improve the process: reminders to providers to submit receipts, bottleneck reports, compliance alerts, etc.

Advanced functionality: data driven decision making

Turn knowledge into actionable insights.

Remaining Budget

1. How much funding has been requested versus approved?

Program Overview

2. How is a department funding across different program types and therapeutic areas?

Success Measurement

3. How does funding look across countries for a single organization?

Historical Measurement

4. How does my funding look year-over-year?

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Do you believe that leveraging compliance data for critical business decisions is possible?

Evolving commercial compliance technology

Clients are asking for a roadmap to implementing AI into the Engage platform

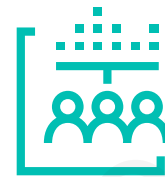**Embedded Intelligence in the HCP Lifecycle**

Reduce Overall Cycle Time

Remove the Guesswork in Meetings & Events Planning

Produce High Quality and Compliant Outcomes

Make Data-Driven Decisions and Eliminate Bias

The Smart Meetings Vision

Leverage technology to plan better events, which produce more a deeply engaged and informed community of healthcare professionals, leading to better treatment of patients and a healthier society.

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Smart Meetings: Attendee management

Create meetings quickly to drive maximum sales lift

Ada recommends the best:

- Venue based on past event success and ratings

- Speakers based on past events and speakers strengths

- Attendees based on attendance history (local and open payments) and predicted lift from attendance
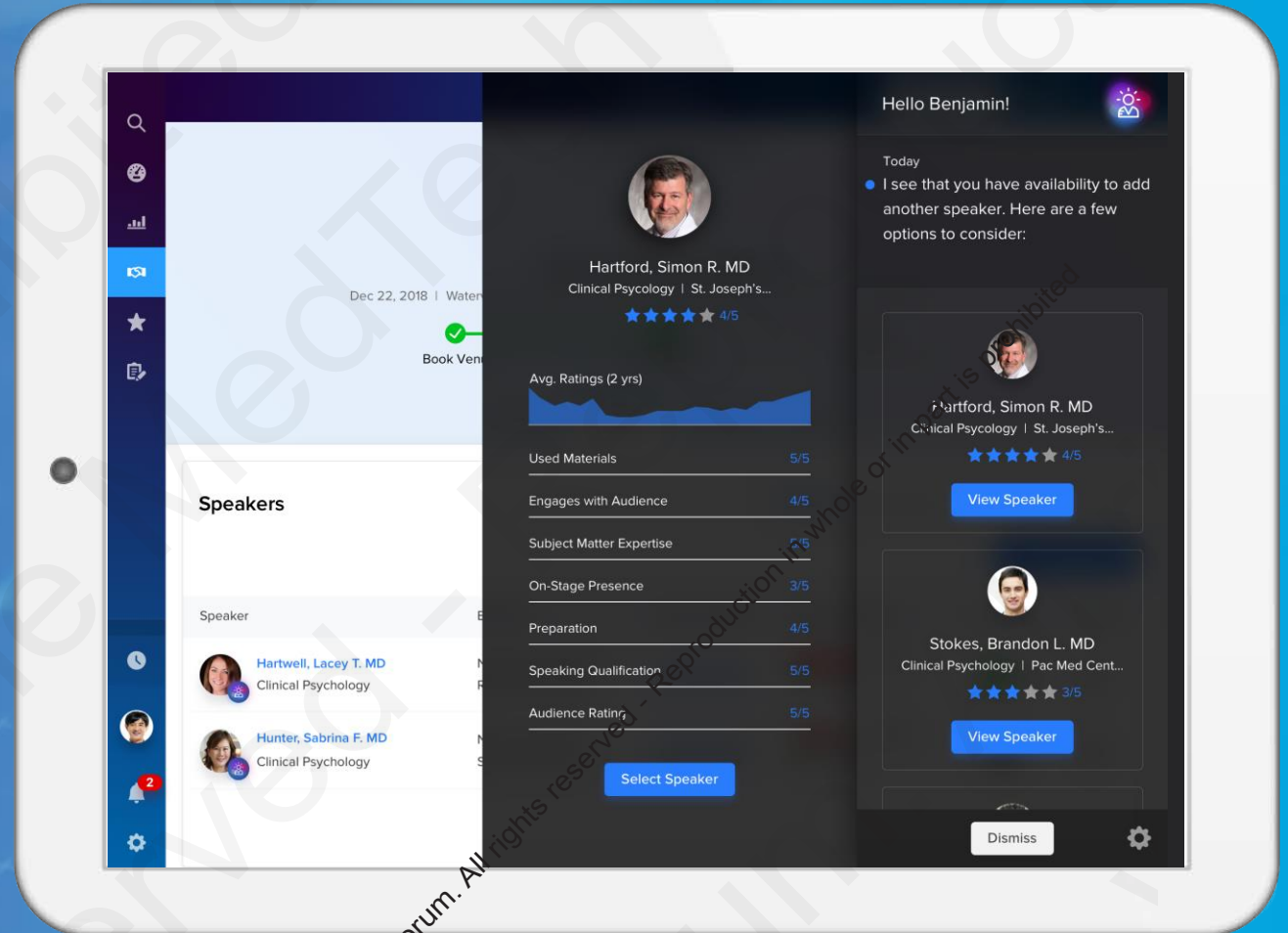
Integrating privacy requirements with overall compliance controls

Protection of personal data under GDPR leads to operational complexity for companies

To meet GDPR requirements, companies must re-think their operational and technical processes and policies;
Core challenge: **How do we make GDPR controls a core part of our compliance programs?**

Above consent management, companies must prove their ability to store and manage personal data (including the right to be forgotten and thus the need to erase data)

Consent is also needed for transfers of values transparency purposes in some countries (HCPs consent for individual disclosure); **At the same time is consent the lawful basis for processing personal data?**

GDPR also requires compliance professionals to be involved in re-thinking the scope of their work and responsibilities

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GDPR necessitates organizational change

DATA

Ist the data we hold compliant?

COMPLIANCE

Can we demonstrate proof of consent?

PROCESSES

Are our processes efficient and reliable?

GOVERNANCE

Do we have mechanisms for continuous compliance across our IT ecosystem?

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How has your organization managed this change?

Key attributes of an optimized and automated process are changing

Direct HCP login through a specific, dedicated link

Ability to share HCP profile creating a simplified user experience—with key data managed in the system, with HCP consent.

Sales Rep or MSL ability to assist the HCP with the signing process

Confirmation guarantees the HCP identity, with voice message, text, or email validation.

Ad-hoc documents crafted to fit HCP needs with static or interactive templates

All signed documents automatically copied to the legal/compliance departments

Multi-language/Multi-country capabilities, including: Spanish, English, French, Italian, German, Polish, Portuguese, Dutch and Czech

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Data privacy, consent collection, and management challenges solved

Case Study

What was the need?

- Undocumented consent to communicate
- Complex IT infrastructure with various types of consent
- Unable to quickly determine if consent was provided or guarantee personal data rights as required by GDPR

How was it addressed?

- Strategic multi-channel marketing campaigns for consent
- Online platform that manages all consent types
- Bi-directional integration with the customer master
- External facing portal allows HCPs to give/modify/revoke consent

What was the outcome?

- Consent rate of 43% for targeted HCPs with trained call center staff, consistently yielding the best results
- GDPR compliance
- Fed consent status throughout the IT network = Unimpeded sales & marketing efforts

And what should we consider further?

- Adaptability to future privacy and consent regulations
- How to be audit-ready with a time-stamped digital audit trail

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Where do we go from here?

How to get started

1. Establish Guidelines—Are you solving Transparency or HCP/O Spend Automation or both?

2. Establish Baseline Collection Requirements

3. Assessment in Each Region / Global Group

4. Deployment Strategy

5. Get To Work (Systems, Change Management, Training, etc.)

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Sample of a cross regional engagement initiative

	Planning	Pre-Approval	Contracting	Payment & Reconciliation	Aggregation	Reporting	HCP/O Consent / Validation
Region/Country 1	As Is	☑	As Is	☑	☑	☑	N/A
Region/Country 2	As Is	☑	As Is	As Is	As Is	☑	As Is
Region/Country 3	☑	☑	☑	☑	TBD	☑	TBD

Illustrative

Deployment strategies – best practices

Fixed Duration Pilot
- Region, Transaction Type, Expedited SDLC, Key Stakeholders, Rapid Prototyping

Allows for Proof of Concept

Requirements Tend to Change During Long Projects Anyway

Consider Cross-Border and Other Global Groups First

Implement Foundational Technology (MDM, ERP, CRM, etc.)

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Key takeaways

Many companies overlook the end-to-end HCP/O engagement process

Building a robust engagement process can unlock business value and improve relationships with HCP/Os

Consider establishing a cross functional Global Engagement team

Ensure you are not forgetting foundational HCP processes, such as FMV

Build data privacy requirements into systems from day one, even if you see no additional business benefit

Don't overcomplicate – focus on gaps and phased roll-outs, don't try to build it all day-one

Don't underestimate change management aspects

Make sure to coordinate with existing/pending compliance programs (ABAC/FCPA, transparency)

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Q & A

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