Healthcare Transparency, Effects on HCP Engagements

at Philips

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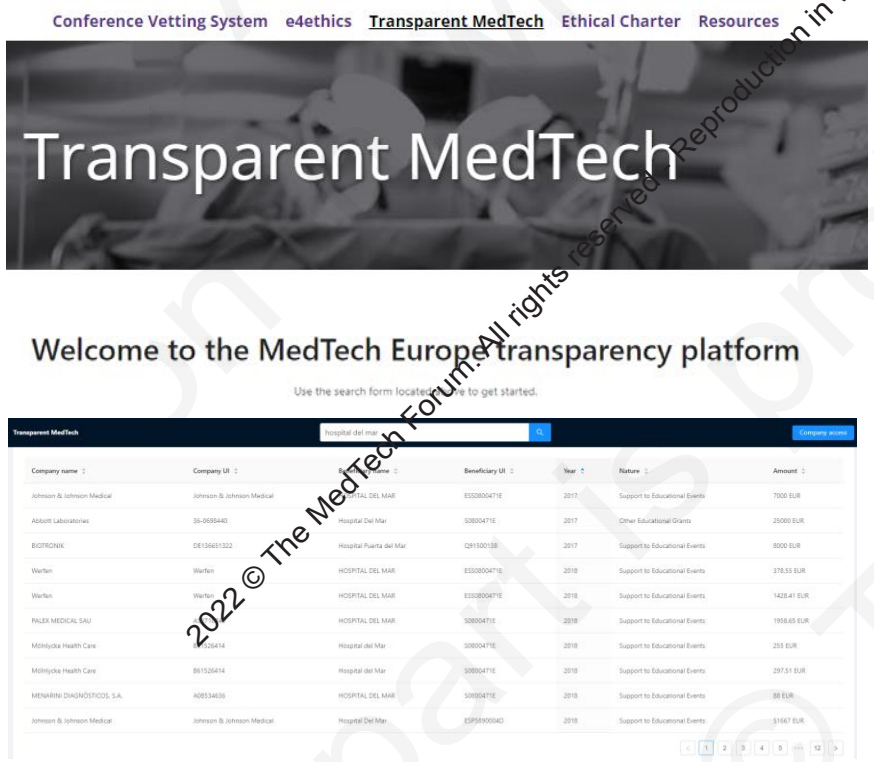
IQVIA MEDTECH

MedTech vs Pharma

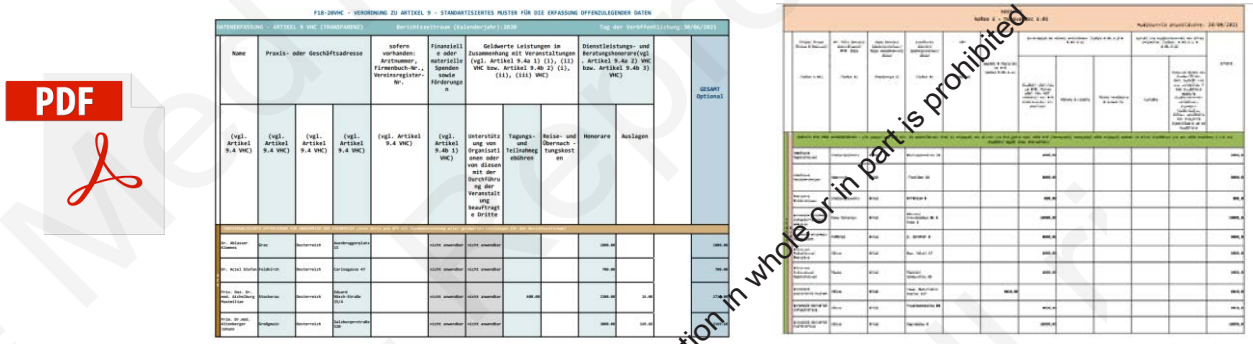
Ethical MedTech
MedTech Europe compliance portal

Enforced
Jan 1st 2018



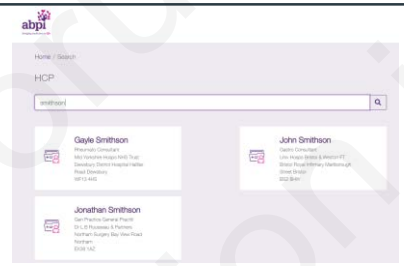
efpia

Enforced
Jan 1st 2015



CONFINDUSTRIA
Dispositivi Medici

abpi



IQVIA MEDTECH

MEDTECH

Global Landscape

IQVIA is monitoring and collecting transparency reporting requirements globally.

37 Countries

5 states (4 in U.S. 1 in Brazil)

31 MedTech Europe Countries

28 Local reports

90 submission deadlines per year

ALL LIFE SCIENCES

Pharma, MedTech, Generics

53 Countries

115+ Report Templates

32+ Laws

47+ Industry Codes

IQVIA methodology

1

Legal Monitoring and Interpretation

- Experienced team of Lawyers and Legal Experts dedicated to monitor and interpret all global regulations impacting Medtech and engagements with HCPs, HCOs, Patients and PTOs

2

Documentation and Publication of Legal/Code requirements

- Documentation for Clients
- Cross Country tables to compare obligations and rules

Global Transparency Regulations Snapshot

Legend: Code Law

COUNTRY / STATE / CITY / COUNTY	INDUSTRY: PHARMA(P), GENERICS(G), MED DEV(MD), OVER THE COUNTER(OTC), COSMETICS(CM), ANIMAL HEALTH (AH)	GOVERNMENTAL BODY/ ASSOCIATION RESPONSIBLE FOR THE DISCLOSURE RULES	LINK TO LOCAL ASSOCIATION WEBSITE OR GOVERNMENT AUTHORITY	REPORT(S) REQUIRED	WAY OF DISCLOSURE AND DEADLINE	JAN 22	FEB 22	MAR 22	APR 22	MAY 22	JUN 22	JUL 22	AUG 22	SEPT 22	OCT 22	NOV 22	DEC 22
AUSTRALIA	P	Medicines Australia (MA)	http://www.medicinesaustralia.com.au	3 Excel files (HCO, Third Party Event, HCP report)	Health Consumer Organisation (HCO) report to be sent via e-mail to MA by April 30; Third Party (TP) Events report to be sent via e-mail to MA by Feb 28 and Aug 31; HCP report to be submitted to the MA Central Reporting System (CRS) one calendar week prior to its publication (i.e. Feb 21, Aug 24). In case the submission date for any of the reports falls on a weekend, they should be submitted on the Friday before		21 (HCP), 28 (TP)		30 (HCO)				24 (HCP), 31 (TP)				
	MD	Medical Technology Association of Australia (MTAA)	https://www.mtaa.org.au/resources/code-of-practice	Format is defined by MTAA each year	Companies may be requested by MTAA to submit via email a report on specific activities identified by MTAA on an yearly basis any time starting from January. The report will not be disclosed to the public but only reviewed for internal monitoring purposes by MTAA												
AUSTRIA	P	Pharmig	http://www.pharmig.at/	1 PDF template	Publication on the Company's website by June 30						30						
	MD	MedTech Europe	http://www.medtecheurope.org/	1 CSV template	Upload to the Central Platform by June 30						30						
	G	Medicines for Europe	http://www.medicinesforeurope.com/	4 PDF templates	Publication on the Company's website by June 30						30						
BELGIUM	P-MD-G-OTC	Agence fédérale des médicaments et des produits de santé (AFMPS)	http://betransparent.be/	1 CSV or Excel Template	Upload to the Central Platform by May 31					31							
BOSNIA-HERZEGOVINA	P	Association of Research-Based Medicine Producers in Bosnia and Herzegovina (UIPL)	http://uipl.ba/	1 PDF template & 1 free format file	Publication on the Company's website and/or upload to Central Platform managed by UIPL by June 30 Companies recommended to disclose between June 20th-30th						30						
BRAZIL - MINAS GERAIS (STATE)	P-MD-G-OTC	Governo de Minas Gerais	http://www.mg.gov.br/	1 CSV template	Law n. 22440 of December 21, 2016: Notification of the ToVs via electronic file to the Authority by the last working day of January	31											
	P-MD-G-OTC-CM	Governo de Minas Gerais	http://www.mg.gov.br/	1 CSV template	Law n. 22921 of January 12, 2018: Notification of sponsorship funding for scientific events via electronic file to the Authority by the last working day of January	31											
BULGARIA	P	Arpharm	http://www.arpharm.org/	1 PDF template	Publication on the Company's website by June 30. Companies recommended to disclose between June 20th-30th						30						
	MD	MedTech Europe	http://www.medtecheurope.org/	1 CSV template	Upload to the Central Platform by June 30						30						

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Transparency Reporting key needs

Transparency Reporting Expertise

- Understanding of regulations and submission deadlines
- Knowledge of data to be collected, and reporting formats
- Automate and verify reporting process

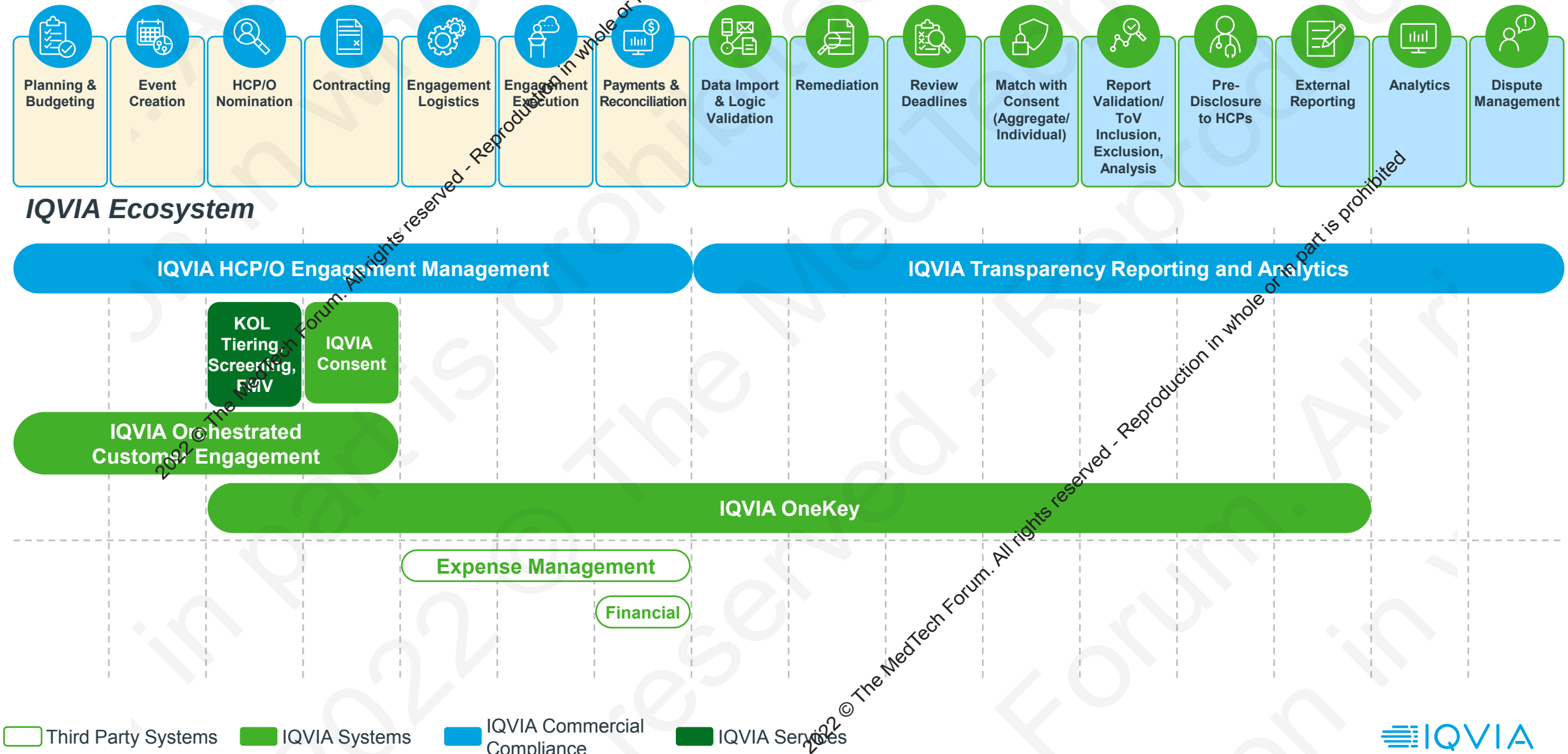
Data Remediation

- Simplify data remediation
- Enable exceptional data management
- Streamline data flows with multiple entities (central team, affiliates, third party)

Transparency Analytics

- Dashboards provide insight into transfer of value and customer record data
- Enable ad hoc analysis design and execution

An end-to-end ecosystem with embedded compliance and streamlined processes

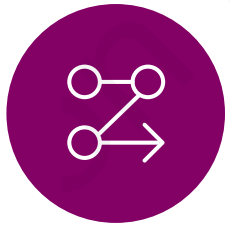


IQVIA Commercial Compliance Portfolio

Integrated offerings supported by technology, consulting services and managed services

Compliance/Risk Assessment

Assess, prioritize, develop and document a tactical compliance roadmap



Engagement

End-to-end **management of HCP/O engagements** from nomination to payment, with advanced business and compliance rules

Virtual and Live Meeting Services

Effective and compliant **meeting management**, **logistics, and strategy** for the life science industry

Transparency Outsourcing

Full outsourcing of reporting from **data validation through submission** and processing

Fair Market Value & Tiering

Determine Fair Market Value of payments to physician consultants, managed markets programs, medical grants and payments for clinical trials

Grants

From grant submission, review, and approval through to payment processing & closeout, our end-to-end solution **covers all funding types.**

Transparency

Captures, collects, integrates, and reports spend – to **meet global transparency requirements**

Consent

Externally facing solution managing **validation, capture, audit** and internal management to meet GDPR requirements

Built on a foundation of domain expertise and industry-leading technology solutions

PHILIPS

IQVIA MEDTECH

Nicolas Albarracin

Senior Legal Counsel - Compliance & Privacy - CISA, CGEIT, CDPSE

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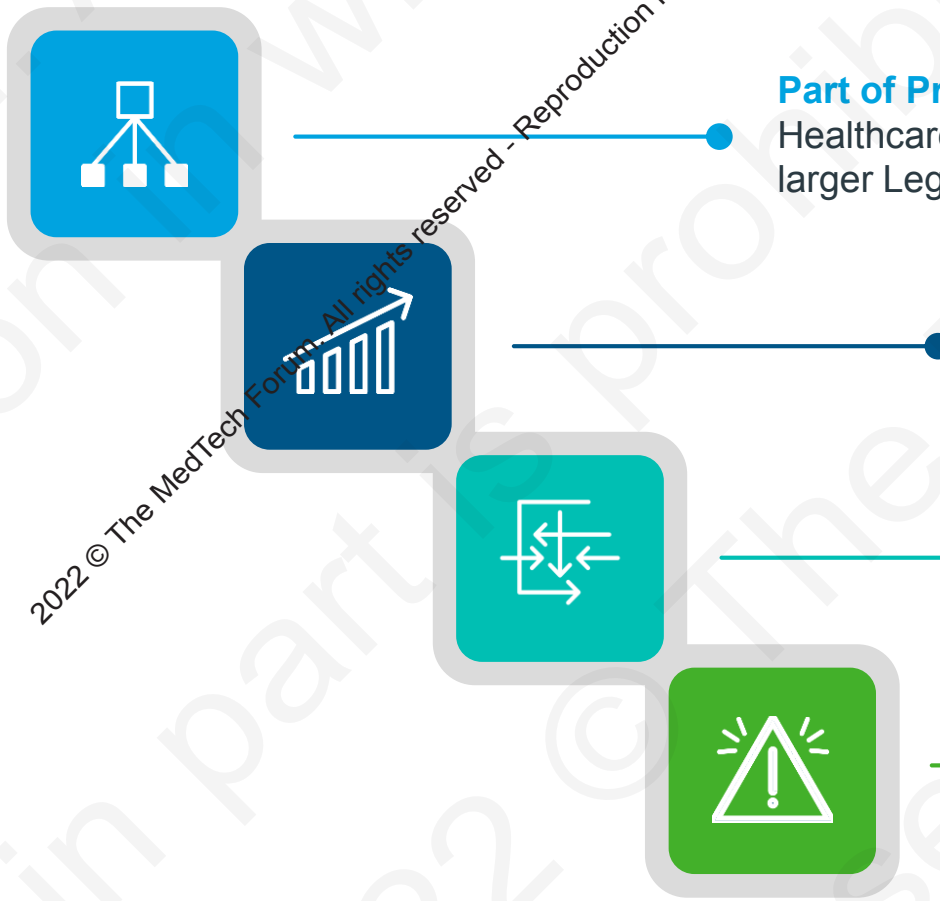
Reason for Philips to start this Global Transparency project



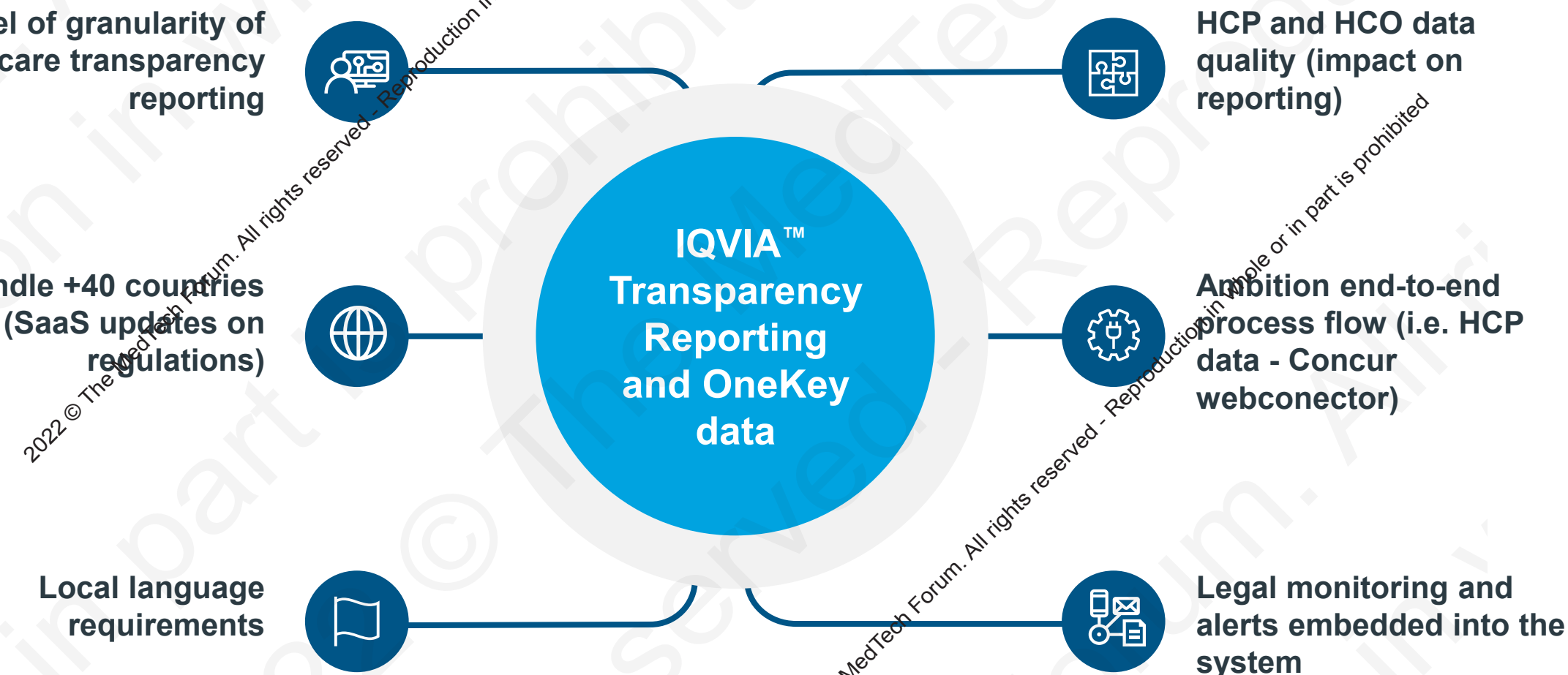
Part of Program
Healthcare Transparency was part of the larger Legal Compliance Program

Increasing regulations
Development in regulatory environments and new jurisdictions (Sunshine Act, Loi Bertrand, codes of conduct from industry association, etc)

Reporting capabilities
Unstructured reporting due to disparate system universe (Sales, Finance, Legal)

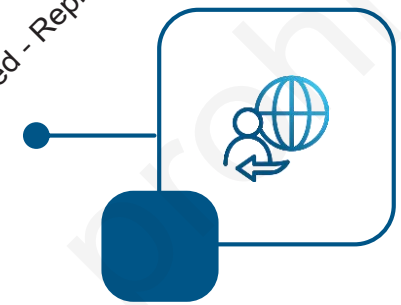
Risk
Mitigate risks under and/or mis-reporting

Why IQVIA



Key objectives of the project

Global system
A comprehensive and truly Global Solution



Supporting Local Requirements
Provide Local Country Officers with standard tooling according to local laws

Visibility
Corporate Visibility and Control (Legal Compliance)

Analytics
Consolidated Reporting and Analytics

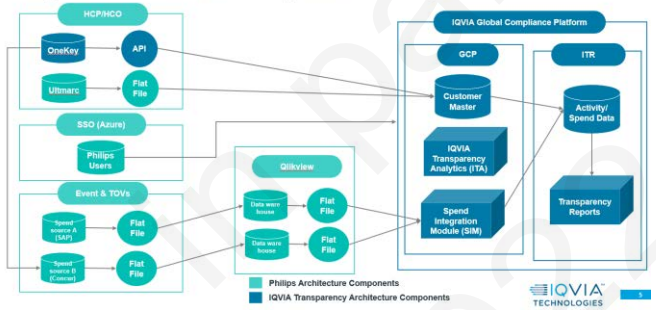
Overall project execution

Global architecture and country roll out

Integrated architecture

- Integrated architecture to maximize validated HCP/O data, optimize processing of Spend data and minimize manual work

Project Solution: IQVIA - Philips ITR Landscape



Wave planning

- Grouping of countries based on region, time-zone, complexity and other business of Philips

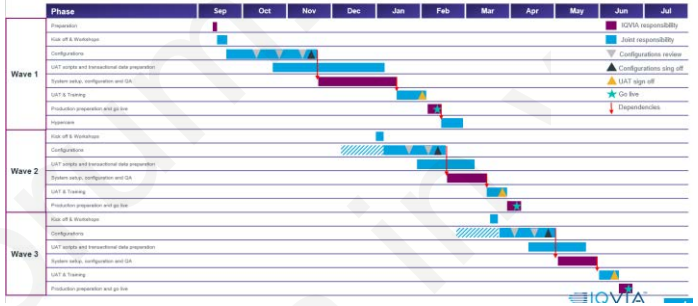
Countries in scope

Wave 1: · Work stream 1 (5 Countries) · Work stream 2 (USA)	Belgium	France	Italy
	Japan	The Netherlands	United States
Wave 2 / Wave 3: · 24 countries *	Brazil	Greece	Croatia
	Czech Republic	Slovenia	Finland
	Germany	Sweden	Hungary
	Poland	Ireland	Norway
	Russia	Portugal	United Kingdom
	Switzerland	Spain	Turkey
Wave 3: · 6 countries	Indonesia	South Korea	Romania
	Saudi Arabia	Colombia	Denmark

Smart Roll out plan

- Overlap of waves to optimize implementation timeline, use of resources and completion in less than 1 year

Philips – IQVIA ITR overall Project Plan



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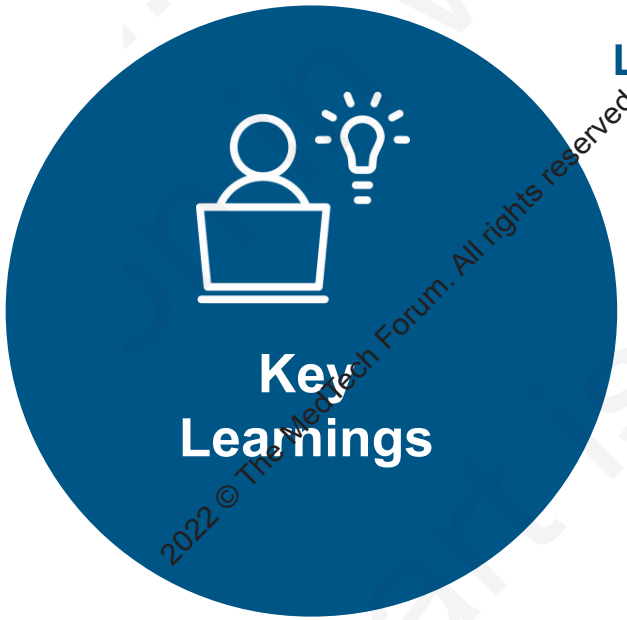

End-to-End

End-2-End means standardization from beginning to end

With a solution supporting the process end-to-end, it's required to standardize the process as well end-to-end.

Local <-> Global

Local countries to participate in Global Implementation

By having participants from all countries directly involved creating more support and acceptance for the implementation and easier adoption of the new technology.

System languages

Local language is key

A system that supports local languages for a global system is key for adopting a new system, especially in countries that without a forced law or code to report.

Thought out governance

Governance (incl. IT) is key in changing regulatory environment

Involve all relevant stakeholders within the project as well as in the leadership team to make decisions and collaborate efficiently.

Country grouping

Country Grouping in waves best for roll-out

Take the time to consider the best grouping of countries and involve them in this as well to optimize the roll out effectiveness.

IQVIA TECHNOLOGIES

Thank you for you attention.

Q & A

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