The Top 10 Evidence Pricing & Access Challenges 2023-2030

...and how to overcome them

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World Evidence Pricing and Access Congress 2023

Healthcare is evolving rapidly

Last year, ISPOR published its Top 10 Trends 2022-23…

1	Real-World Evidence
2	Value Assessment
3	Health Equity
4	Healthcare Financing
5	Patient Engagement
6	Drug and Healthcare Pricing
7	Public Health
8	Cross-Country Health Technology Assessment Cooperation
9	Health Data
10	Artificial Intelligence and Advanced Analytics

This triggered a huge interest amongst our clients around the evidence, pricing and access challenges these will bring, and what it will take to overcome them.
This presentation summarises the results of our research

https://www.ispor.org/heor-resources/good-practices/article/ispor-2022-2023-top-10-heor-trends

01

Methodology

Insights were elicited using a 2-Cycle Delphi approach

Delphi Cycle 1:

Generation of a list of the key challenges:

- Evidence
- Pricing
- Access

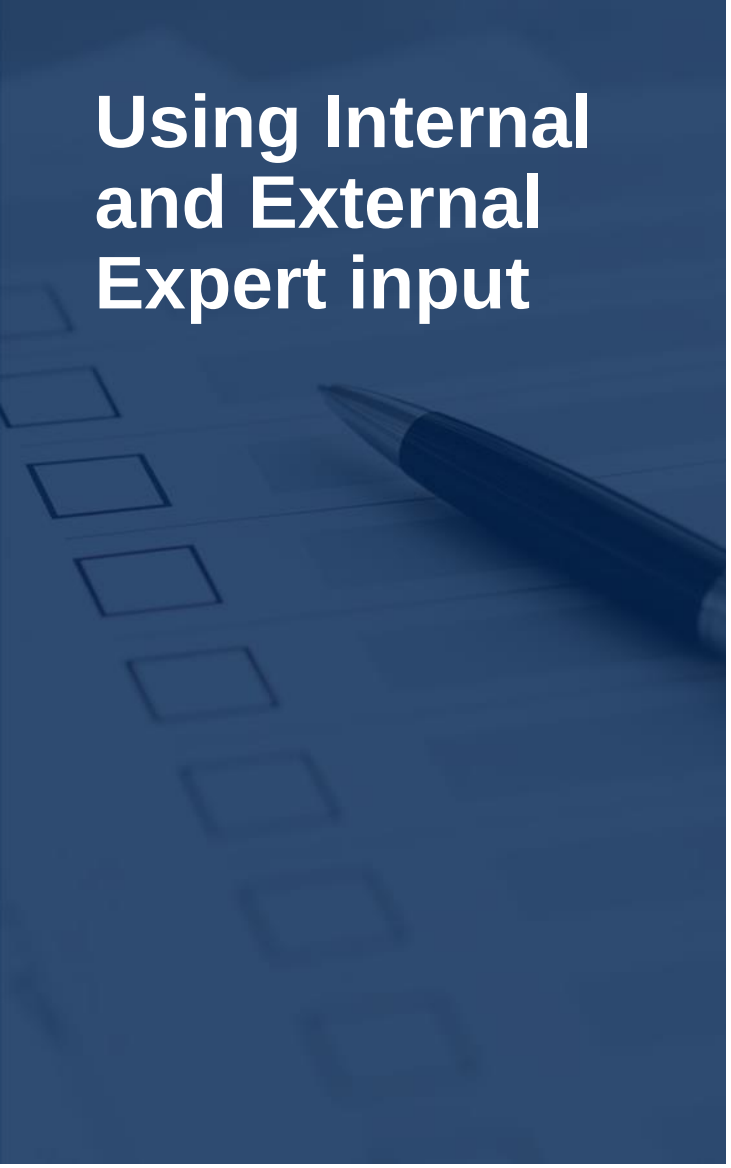
over the period 2023-30 in oncology and immunology.

No limits on numbers of challenges

Delphi Cycle 2:

- Results of Cycle 1 shared amongst participants
- Participants confirm or amend their input
- Challenges clustered
- Barriers identified
- Solutions identified

Using Internal and External Expert input



Internal:

- Ipsos Market Access Teams in EU, US, and APAC
- Ipsos Oncology Centre of Expertise
- Ipsos Autoimmune Centre of Expertise
- Ipsos Global Oncology Monitor (Syndicated Real World Evidence)
- Ipsos Autoimmune Therapy Monitors (Syndicated Real World Evidence)
- Ipsos Molecular Diagnostics Monitor
- Ipsos Trends and Foresight

External:

- Payer experts in immunology and oncology via 2 roundtables undertaken for clients

Participants: Internal: n=35 External: n=6

The scope included

The Complete Lifecycle Pathway

- From drug discovery to loss of exclusivity (LoE)

The Digital Contribution

- Digital health technologies based on monitoring, intervention, predictive analytics, and AI

The Genomic Contribution

- **Patient Selection** informed by genomics and molecular diagnostics
- **Assessment of Co-dependent Value (Rx-Dx)** where biomarkers have a role

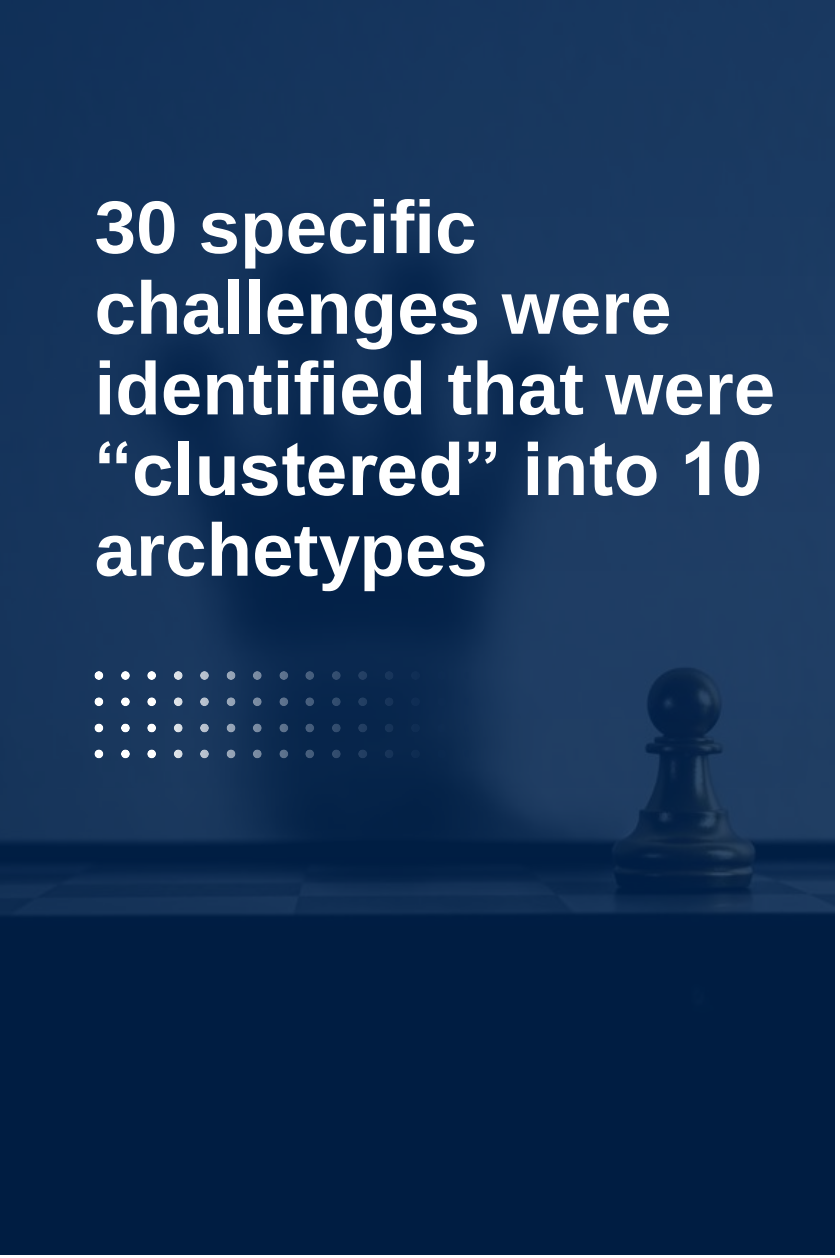
Consideration of Value Attribution

- Where value is delivered by multi-component disease management rather than by drugs or interventions in isolation

02

Challenges

30 specific challenges were identified that were “clustered” into 10 archetypes



01	AFFORDABILITY
02	EVIDENCE
03	ASSESSMENT
04	PRICING
05	DIFFERENTIATION
06	SEQUENCING
07	PERSONALISATION
08	VALUE ATTRIBUTION
09	PORTFOLIO OPTIMISATION
10	PACE OF CHANGE

- **The majority of the 30 specific challenges are applicable to most therapy areas, not only oncology and immunology.**
- **The largest cluster (7/30) comprised PERSONALISATION challenges (genomic and digital, rather than classical therapeutic).**
- **The majority of these challenges are not new.**

Affordability

1

In-Country: Alternative Funding Models

Acceptability of innovative managed entry agreements, subscription models, and solutions from financial services industry

2

Between-Country: Equitable Affordability

Addressing affordability differences between countries. E.g., **Equity Based Tiered Pricing (EBTP)** based on gross national income (GNI) per capita adjusted for purchasing power parity.

3

High Price Density In Large Populations

Reimbursement of ATMPs (cell and gene therapies) in common diseases where there will be a very high upfront cost, often single payment.

Evidence

4

Availability, Accessibility & Acceptability

RWE, digital health technology data, advanced analytics, and modelling in Payer/HTA assessment

5

Multi-Source Data Integration

Building a robust value story integrating **an abundance of sometimes conflicting and contradictory data.**

6

Tumour Agnostic Licensing

Building a robust value story in the **absence of data**

7

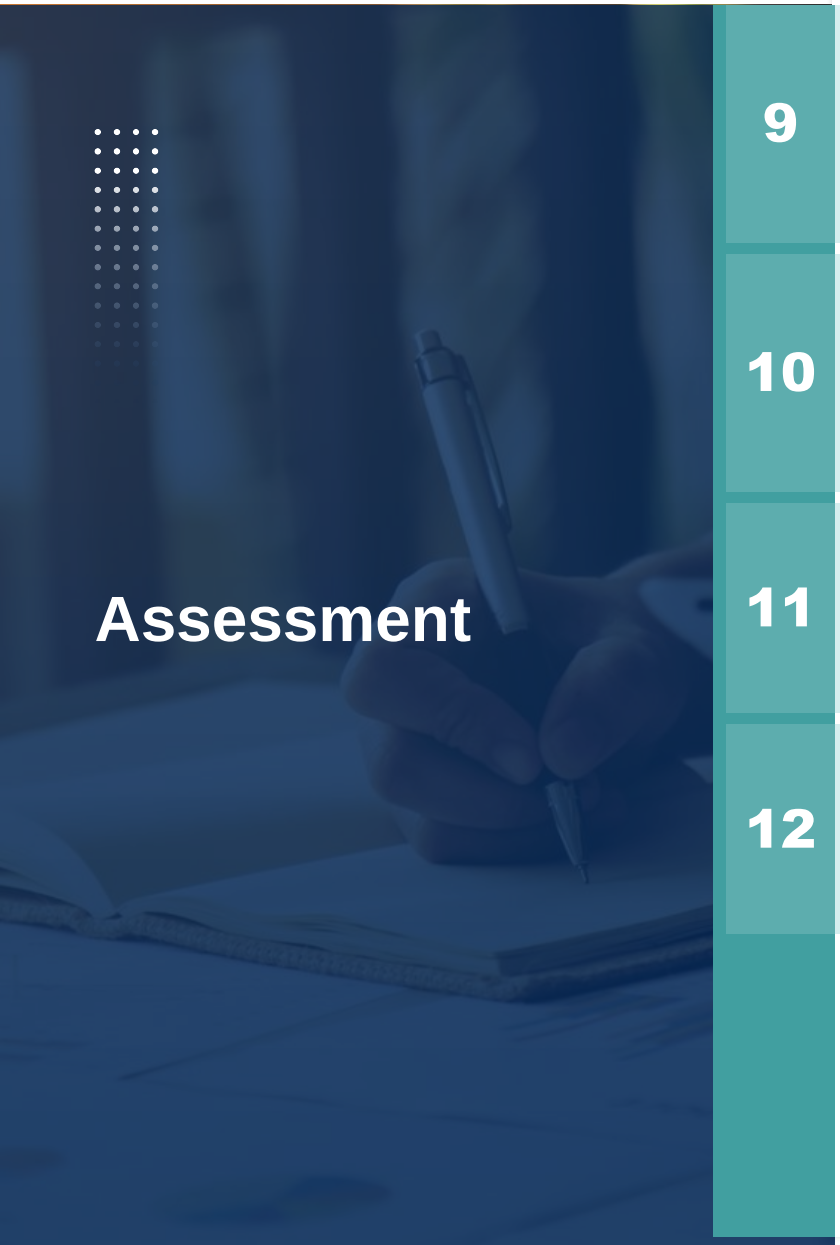
Regulatory Versus Payer Requirements

Clinical trials design in a fast-changing, often multicomponent environment.

8

Ethical And Legal: Data Ownership, Use And Abuse

Ethical and legal challenges over ownership and use of data, and regulatory challenges emerging from interventions that are driven by automated analytic algorithms/machine learning/artificial intelligence



Assessment

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“Marriage” Of The Regulator And The Payer

Closer integration of regulatory and HTA, common clinical assessment, EU HTA harmonisation, DARWIN EU RWE coordination. Harmony or hell?

10

Integration Of “Forgotten or Ignored Value” In HTA Assessment

Cost savings outside the health system, reduction in uncertainty, value of hope, real option value, insurance value, and scientific spill-overs

11

Linking Endpoints And Outcomes

Extrapolation from surrogate endpoints to disease modification, CV risk reduction and/or organ failure

12

Unmet Need And Burden Of Illness

A widening gap. Payers perceive there is little unmet need and have a low willingness to pay (WTP). Manufacturers believe there is high unmet need and have high expectations for both price and volume

Pricing

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Price Contagion

Establishing a value-based price when all around you are losing exclusivity

14

Price Modification

Adjustment of price to ensure affordability and cost-effectiveness of combinations, triples, and therapy stacks

Differentiation

15

Establishing Differentiation When Products Are The Same Or Similar

Critical for commercial success post LoE for originators, generics and biosimilars of blockbuster products

16

Drug Delivery Differentiation

The trade-off of duration of effect, patient preference, convenience, compliance and clinical / economic real-world outcomes

Sequencing

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Treatment Order Sequencing

Measuring the value of a treatment sequence rather than in a single line of therapy. Pricing to the end-goal: A therapy is launched in late line but the ultimate goal is 1st line. How to price in a way that may dilute initial revenues, but under uncertainty eventually maximises lifecycle revenues.

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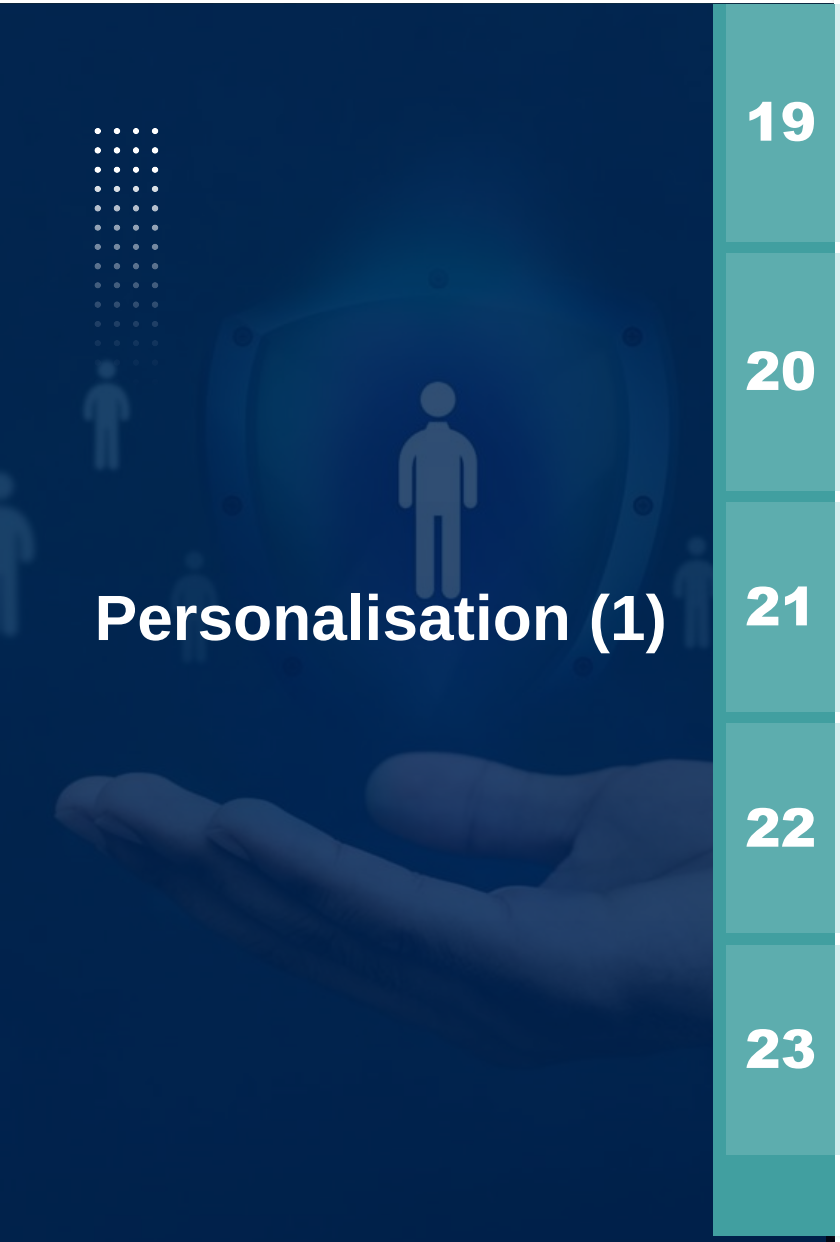
Early Detection And Diagnosis

Early screening initiatives face challenges in the real world. For payers and policy makers (around the benefit threshold) and for patients (when there are no treatments accessible / available)



Personalisation (1)

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Dr Google

The increasing role of the patient: Knowledge, expectations, increased involvement in decision-making but NOT correlated with patient willingness to pay. Advancement of freely available information through web-based bots e.g., ChatGPT

20

Making Digital Healthcare Smarter

Integrating monitoring intervention and prediction into disease management

21

Molecular Diagnostics-Informed Drug Commercialisation

Choosing a commercialisation strategy for products that are good in all patients, better in some

22

Integrating Molecular Diagnostic Testing Into Routine Clinical Practice

Overcoming the barriers to access, funding and use of diagnostic testing

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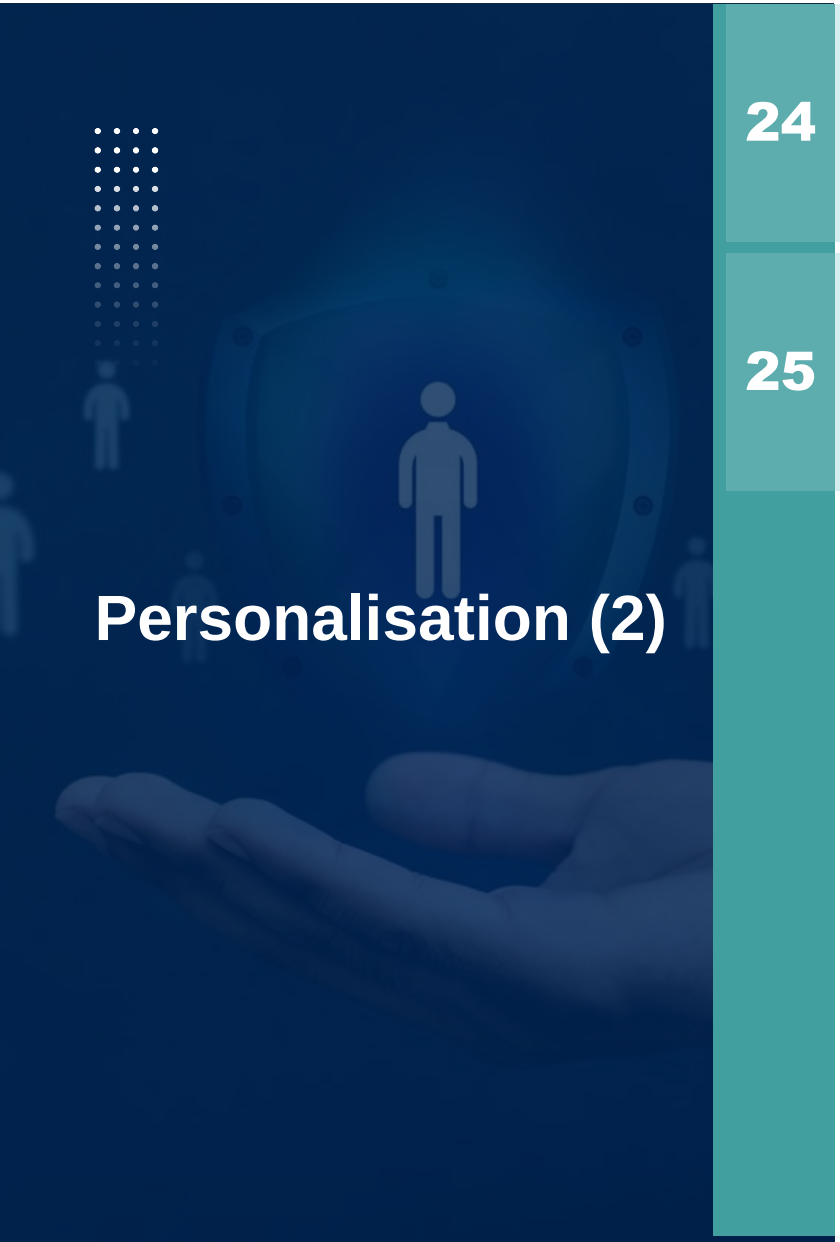
When, And In Whom, To Undertake Biomarker Testing

Academic guidelines are often split between recommending comprehensive genomic profiling for all, as early on as possible, and reserving these for later-line patients, noting the challenges if patients are not able to access the targeted therapies they're identified as being candidates for



Personalisation (2)

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Keeping Up With The Science

The cost of comprehensive molecular/genomic testing will drop and the number of test providers will increase.. Physicians and payers will need to change behaviours, adopt new practices, keep up with clinical recommendations and reimbursement/coverage,

25

Digital Pathology

Adoption of digital workflows, digital pathology / digital diagnostics solutions. Keeping up with AI, machine learning, inter-connectedness, and information-sharing that digital pathology will allow. Challenge to incorporate diagnostics and digital pathology more closely into clinical trial design

Value attribution

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Cost Effectiveness

Adaptive pricing and reimbursement of combination therapies and “stacks”

27

Fair Allocation Of Reimbursement

Fairly reimbursing value contribution in a world where digital health and genomics/biomarker informed disease management become more closely connected

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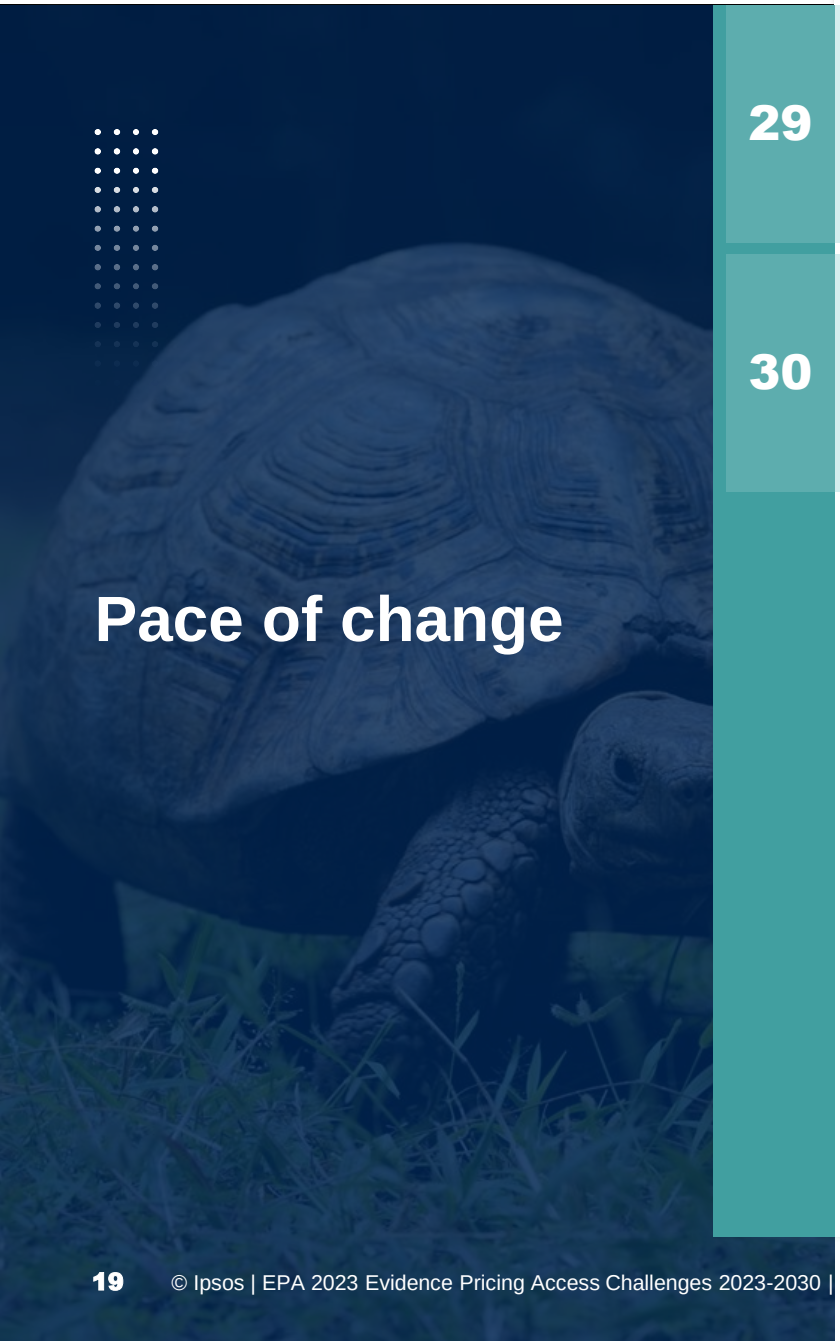
Portfolio optimisation

Moving From The Value Of The Brand To The Value Of The Portfolio

Assessing costs and consequences of treatment strategies involving several of a company's assets. Marketing disease management solutions. Ensuring full compliance to ensure no inducement to prescribe



Pace of change

29

30

Tortoise And Hare

Evolution of healthcare systems and drug development moves at a glacial pace whilst technology moves significantly faster. Risk of by the time a technology is assessed, approved, and granted access it is out of date

Corporate, Political And Societal Amnesia

There are very few challenges that are new. Companies forget that! Much can be learned from how these challenges were addressed, both successfully and unsuccessfully, in the past via analogue analyses

03

Conclusions and Solutions

These 30 challenges involve multiple stakeholders & capability requirements

MULTIPLE STAKEHOLDERS

Politicians

Physicians

Patient

Pathologists

Payers

Pharma

CAPABILITY REQUIREMENTS

- Willingness to Change
- Ability to Pay
- Willingness to Pay
- Willingness to Test & Treat
- Willingness to be Treated
- Willingness to Invest
- Ability to Access
- Willingness to Cooperate
- Ability to Integrate Data

Ref: Adapted from "The Power of Holistic Insights. An Ipsos POV" Teale, Franceschetti, Levent, Duncan, November 2022

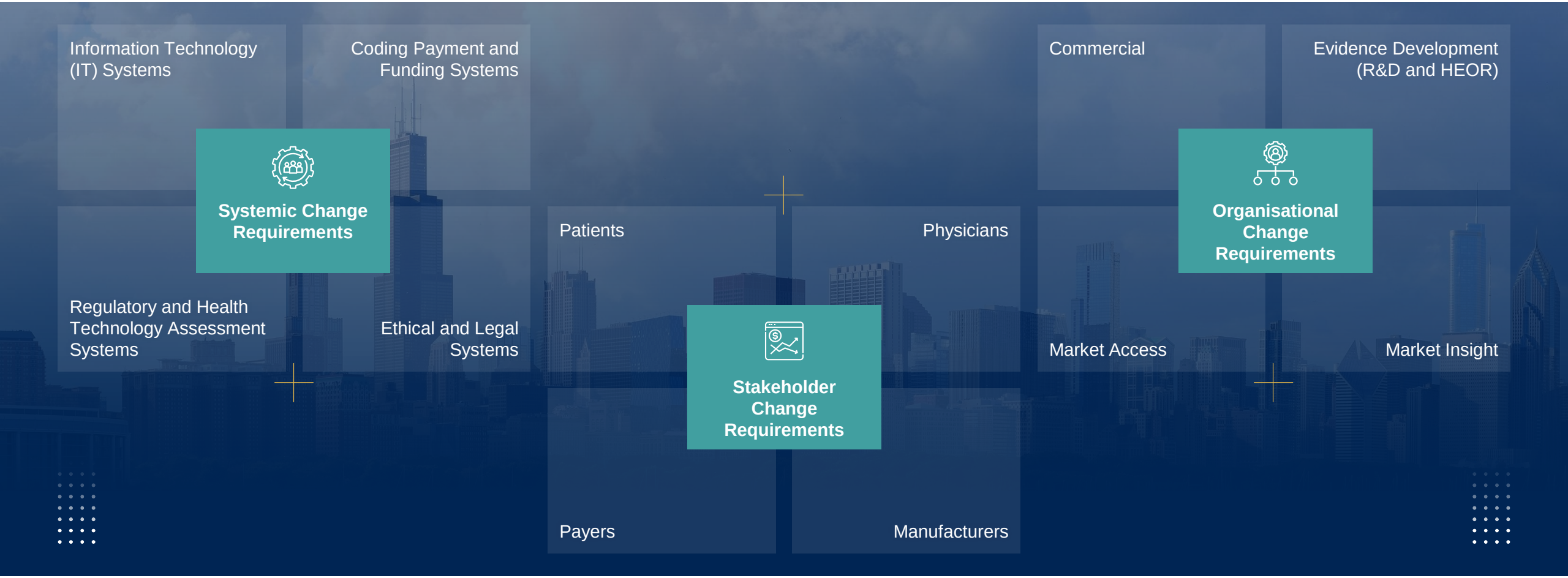
This leads to the CONCLUSION:

These challenges cannot be solved in isolation, in a single company or departmental silo, based on single data sources. Solutions are easy…implementation is not!

There are at least 3 critical factors for successful implementation of solutions

1. **CHANGE – Systemic, Stakeholder, Organisational**
2. **COLLABORATION – Between Stakeholders**
3. **INTEGRATION – Of Data**

Change will be required to overcome the evidence availability, accessibility, and acceptability challenge



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Strategic collaboration between manufacturers and data providers will be needed to access data

2016

AstraZeneca becomes a Founding Enterprise Partner for CancerLinQ.

2017

2018

Roche acquires Flatiron Health, granting them access to 2.2 million active patient records.

Aetion and FDA enter partnership to replicate 30 published RCTs with RWD analyses.

2019

2020

Aetion & Cegedim Health Data announce partnership to integrate Cegedim's European RWD to Aetion's Evidence Platform which analyses RWD including claims, electronic health record & registries.

ConcertAI and Novartis enter collaboration to use RWD with three key objectives: 1) Improved RCT design 2) RWD-based label extensions & new indications 3) Accelerated market access

2021

AstraZeneca publishes RWE study results conducted with CancerLinQ titled 'Real-world clinical outcomes of patients with BRCA-mutated (BRCAm) HER2-negative mBC'1.

2022 /3

Multiple Artificial Intelligence collaborations

With the establishment of these relationships, manufacturers can readily access RWD which they can utilise across their portfolios.

Multiple source data integration will be required

Market insight

- Proprietary syndicated data
- Data analytics with traditional market research
- Behavioural science
- Creative labs
- Social Intelligence Analytics (SIA)

Third Party External Sources

- Prescription data
- Electronic medical records (EMRs)
- Health resource utilisation (HRU)
- Claims data
- Real-time / wearable data
- Social media data

Manufacturer's Internal Data

- Customer relationship data (CRM)
- Internal resource allocation

Ref: Ipsos Multi Source Data Strategy – Internal presentation

In summary

The greatest number of challenges and opportunities in 2023-30 will lie in the PERSONALISATION of healthcare – the integration of digital, genomics, and analytics

- More and more alternative, often unstructured, data sources will be available and acceptable to use.
- Increased levels of collaboration will be required to access these

Significant systemic, stakeholder, and organisational barriers will need to be overcome in order to successfully address Evidence Pricing & Access challenges in all therapy areas in 2023-30

THANK YOU.

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Ipsos is a global insight, analytics and advisory partner to the healthcare sector. Our multi-disciplinary teams deliver integrated services and proprietary real-world evidence across the product lifecycle

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Chris Teale brings extensive practical and academic experience, across both Marketing and R&D, from a 30-year career within the pharmaceutical industry, having held a number of leadership positions at both Global and European level at AstraZeneca, Allergan, Novartis and Fisons.

Within Ipsos Market Access, Chris leads on the European Oncology and Personalised Healthcare (PHC) thinking and is also Lead on Global Biosimilar Strategy and War Gaming / Competitive Simulation. His specialist areas of focus are policy influence in Autoimmune Diseases and Oncology; and innovative approaches to pricing and market access.

Chris gained a BSc degree in Mathematics from Newcastle University, and also studied at Loughborough University and INSEAD Business School. He is an occasional lecturer on health economics and pricing and reimbursement at Kings College London and University of California (San Diego).