#ISPORAnnual

ISPOR

SUMMARY REPORT

7-10 May 2023
Boston, MA, USA

ISPOR 2023
#ISPORAnnual

Remap

CONTENTS

DAY 1 PLENARY

GLOBAL FOCUS ON AFFORDABILITY AND INWARD INVESTMENT – WHAT DOES IT MEAN FOR HEOR?

INTRODUCTION

The opening plenary session was led by Dr. Sam Roberts (Chief Executive of NICE), who moderated a discussion on affordability, inward investment and the consequences for HEOR. Dr. Roberts began the discussion by acknowledging growing health disparities and rising healthcare costs globally. Unsurprisingly, the Inflation Reduction Act (IRA) was a major talking point amongst the panellists.

KEY DISCUSSION POINTS

- Dr. Meena Seshamani, a representative from CMS, outlined the various provisions in IRA to address affordability issues, and the additional considerations:
  - Personal affordability was described as a major obstacle to access to treatment in the US. The importance of value and innovation is limited if people cannot afford the medication.
  - The focus on drug affordability is a wider part of change in the CMS program, driven by the desire to spend healthcare dollars in a smarter way
- However John O'Brien, a Senior Director at the National Pharmaceutical Council, argued the impact of IRA to manufacturers may be underestimated
  - O'Brien described the changes as a 'watershed moment' in the US
  - Proposals around indication expansion and orphan designations were of particular concern to manufacturers, as well as a perceived lack of transparency in the process and the inability to engage with the relevant government departments
- Dr. Seshamani believed the HEOR industry will be of critical importance in the changing US market
  - Two major areas of research Dr. Seshamani highlighted that were the need for improved assessments of RWE, and research understanding the impact of changes to the US' dynamic drug market from the perspectives of all stakeholders.
  - Other members of the panel agreed that the utilisation of RWE has 'barely scratched the surface'.

DAY 2 PLENARY

AI WANTS TO CHAT WITH YOU: ACCEPT OR IGNORE?

INTRODUCTION

The topic of the plenary session for Day 2 of ISPOR revolved around the potential use of AI in health economics and research outcomes (HEOR). Previously identified by ISPOR as one of the top 10 HEOR trends for 2022-2023, AI has rocketed into the public consciousness with the development of easily accessible large language models (LLM) such as ChatGPT.

Whether the mention of AI has you dreaming of a digital utopia, or brings you out in a cold sweat at a Skynet takeover, there is no doubt that it will play a foundational role in the future of healthcare. Below is a summary of the fascinating conversation that played out at the second plenary session at this year's ISPOR Annual.

THE CHATGPT PHENOMENON

- The panellists agreed that the biggest change introduced by ChatGPT is a greater public awareness of AI, with its wide accessibility providing users direct insights into the potential for AI.
- Putting these type of large language models into production, and bringing machine learning to millions of people, is associated with managing risks.
- As part of managing this risk, there needs to be baseline understanding of what AI models do, in what areas they work well and what areas they work poorly (and why).
- Trust was an interesting area of discussion of the plenary. It was raised that some patients may not trust the outputs of AI models (e.g. may not follow up recommendations, such as meeting with a specialist). Questions were raised around how lack of patient trust in AI can be taken into account in economic modelling, and how inherent bias within LLMs could be tackled.

- Other panellists also raised the challenge and possible inequalities in AI models operating in countries with lesser spoken languages
- It was stated that an obstacle in the wider scale AI implementation could be the mismatch in knowledge between stakeholders (e.g. model developers, regulators, providers and patients). HEOR can work to close these gaps.

POTENTIAL USAGES OF AI BY HCPS AND HEOR

- The panellists discussed how AI could be integrated into patient care, both at home and at the clinic.
- One example was the potential ability to monitor patients at home (e.g., for chronic conditions). In this scenario, healthcare providers would be receiving information from the patient (e.g., via voice/text message) and AI would be able to map the language used by the patients onto existing, validated instruments.
- This would allow healthcare providers to collect information every day, avoid the need to bring the patient into the clinic (and fill in repetitive questionnaires) and limit the resource implication of collecting such information.
- Panellists also raised another example of the utilisation of AI – a potentially huge uptake of 'ambient technology' over the next five to ten years. Such technology would allow conversations between patients and clinicians to be recorded and analysed to provide a new source of real-world evidence. These conversational insights are currently either lost or summarised ineffectively in patient notes.
- Currently, the most likely place that AI will complement the healthcare services will be in the 'business' of healthcare: speeding up and improving efficiency of administration, operations, coding and marketing. For the physicians themselves, it could be the summarisation of large amounts of patient data.
- However, one of the panellists cautioned that there must always be a 'human in the loop' to interact directly with the patient. The potential for AI could be so transformative in delivering healthcare that the education of future HCPs will have to be reinvented.

PATIENT-REPORTED OUTCOMES

- The use of AI in collecting and analysing PROs were a major thread of the conversation, especially in the potential ability to speed up identifying and understanding variables and cofounders.
- Since PROs are collected and coded already by humans, they are seen as 'low-hanging fruit' for the wider implementation of AI.
- For example, the process of extracting information from clinical notes as part of a chart review could take months: LLMs could do this in a few days or even hours.
- There is a need for HEOR to understand what is going into the model, and how the model should be interrogated and fine-tuned, and how often such models should be retested.
- Panellists also outlined the need to balance demands for more patient data (e.g. more specific metadata) and patient privacy. Moving forward, there is a clear need to establish industry best practices and frameworks or checklists.
- The overall goal is to move towards validated instruments which avoid risk of bias and are transparent enough for regulators to understand.

KEY TAKEAWAYS

1. Expect to see lots of innovation in large language models, with more access for HEOR professionals. As HEOR works in the patient domain, the focus should be on innovation that is safe.

2. The time for collection and analysis of RWE data could go from months to days – this could be revolutionary in the understanding of drug effectiveness.

DAY 3 PLENARY

ISSUES AND SOLUTIONS WHEN ESTIMATING TREATMENT EFFECTS USING US ELECTRONIC HEALTH RECORD DATA

INTRODUCTION

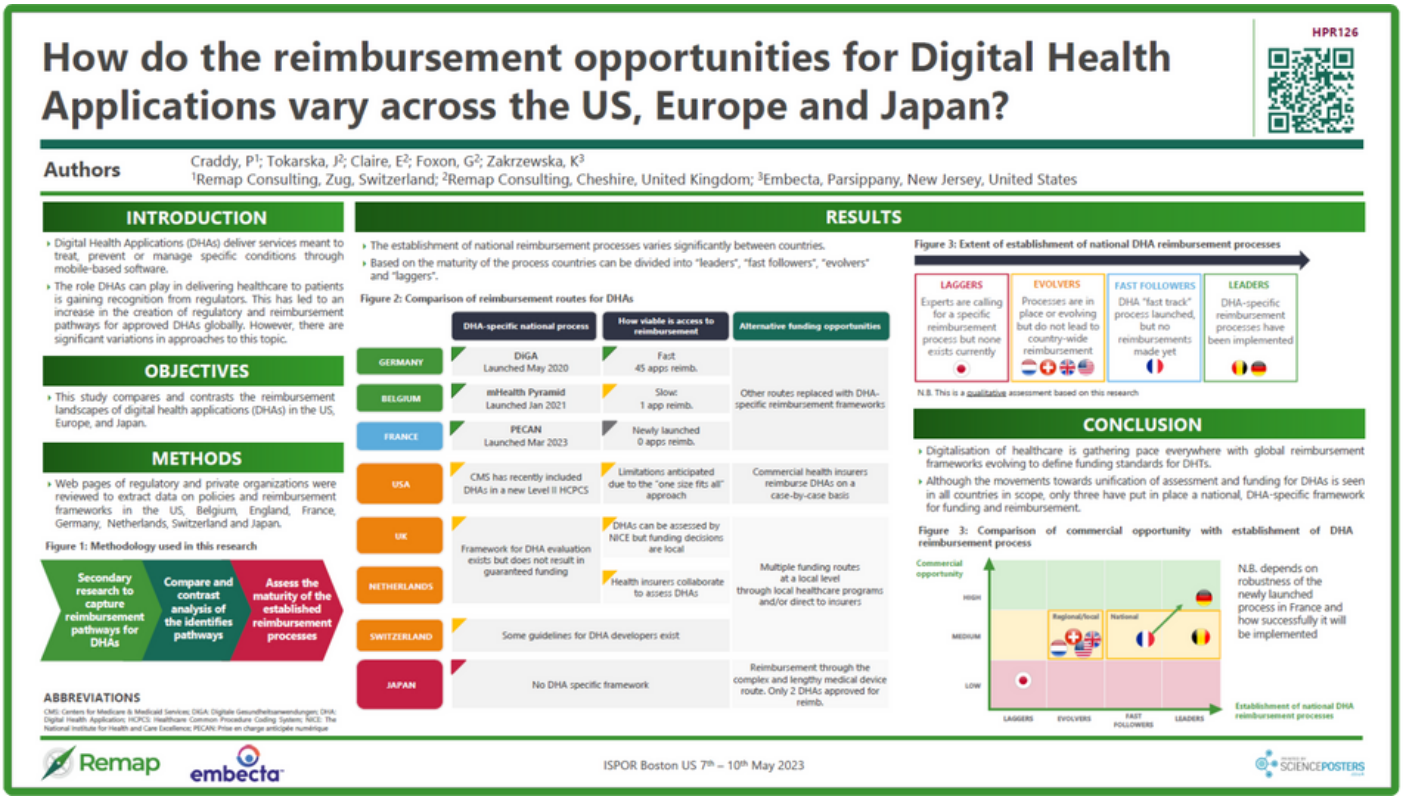
The use of electronic health records (EHRs) as real-world data (RWD) sources for understanding the effectiveness and safety of medicinal products is challenging. The final plenary session at ISPOR 2023 discussed issues and solutions for estimating treatment effects using US EHR data.

KEY DISCUSSION POINTS

- Covariate adjustment is important in RWE studies, and the session discussed approaches for adjusting confounding variables in large data structures involving linked claims data with EHRs.
- Recommendations from the session included generating pre-exposure features, using ultra high-dimensional covariate data for improved confounding adjustment, and considering overfitting the treatment model for confounder selection.
- The use of active comparators in study design can help reduce bias, as demonstrated in a study on bariatric surgery and major adverse cardiovascular events.
- Proper study design, careful data assessment, and emulation of randomized trials were highlighted as ways to mitigate bias in RWE studies.
- EHR data provenance, which involves considering the differences in information density across patients, should be taken into account when conducting a study to avoid bias.
- Analytical strategies such as ad hoc adjustment for the number of observations, joint modeling, and multiple outputation can be used to account for selective observability/informative visit process in EHR data.
- Dealing with missing data requires outlining assumptions, integrating routine diagnostics at the study design level, and checking the robustness of assumptions in sensitivity analyses.
- The future of EHR data in RWE studies involves the potential use of tools like natural language processing to extract more information from unstructured records and overcoming the problem of fragmented information within the healthcare system.
- Data-driven machine learning tools have the potential to improve analyses, but expert background knowledge combined with these tools is important.

RESEARCH POSTER

WE'RE PLEASED TO HAVE PRESENTED THE BELOW PIECE OF RESEARCH AT ISPOR ANNUAL, IN PARTNERSHIP WITH EMBECTA.



How do the reimbursement opportunities for Digital Health Applications vary across the US, Europe and Japan?

HPR126

Authors: Craddy, P[1]; Tokarska, J[2]; Claire, E[2]; Foxon, G[2]; Zakrzewska, K[3]
[1]Remap Consulting, Zug, Switzerland; [2]Remap Consulting, Cheshire, United Kingdom; [3]Embecta, Parsippany, New Jersey, United States

INTRODUCTION

- Digital Health Applications (DHAs) deliver services meant to treat, prevent or manage specific conditions through mobile-based software.
- The role DHAs can play in delivering healthcare to patients is gaining recognition from regulators. This has led to an increase in the creation of regulatory and reimbursement pathways for approved DHAs globally. However, there are significant variations in approaches to this topic.

OBJECTIVES

- This study compares and contrasts the reimbursement landscapes of digital health applications (DHAs) in the US, Europe, and Japan.

METHODS

- Web pages of regulatory and private organizations were reviewed to extract data on policies and reimbursement frameworks in the US, Belgium, England, France, Germany, Netherlands, Switzerland and Japan.

Figure 1: Methodology used in this research

Secondary research to capture reimbursement pathways for DHAs → Compare and contrast analysis of the identifies pathways → Assess the maturity of the established reimbursement processes

ABBREVIATIONS

CMS: Centers for Medicare & Medicaid Services; DiGA: Digitale Gesundheitsanwendungen; DHA: Digital Health Application; HCPCS: Healthcare Common Procedure Coding System; NICE: The National Institute for Health and Care Excellence; PECAN: Prise en charge anticipée numérique

RESULTS

- The establishment of national reimbursement processes varies significantly between countries.
- Based on the maturity of the process countries can be divided into "leaders", "fast followers", "evolvers" and "laggers".

Figure 2: Comparison of reimbursement routes for DHAs

	DHA-specific national process	How viable is access to reimbursement	Alternative funding opportunities
GERMANY	DiGA Launched May 2020	Fast 45 apps reimb.	Other routes replaced with DHA-specific reimbursement frameworks
BELGIUM	mHealth Pyramid Launched Jan 2021	Slow: 1 app reimb.	
FRANCE	PECAN Launched Mar 2023	Newly launched 0 apps reimb.	
USA	CMS has recently included DHAs in a new Level II HCPCS	Limitations anticipated due to the "one size fits all" approach	Commercial health insurers reimburse DHAs on a case-by-case basis
UK	Framework for DHA evaluation exists but does not result in guaranteed funding	DHAs can be assessed by NICE but funding decisions are local	Multiple funding routes at a local level through local healthcare programs and/or direct to insurers
NETHERLANDS		Health insurers collaborate to assess DHAs	
SWITZERLAND	Some guidelines for DHA developers exist		
JAPAN	No DHA specific framework		Reimbursement through the complex and lengthy medical device route. Only 2 DHAs approved for reimb.

Figure 3: Extent of establishment of national DHA reimbursement processes

LAGGERS	EVOLVERS	FAST FOLLOWERS	LEADERS
Experts are calling for a specific reimbursement process but none exists currently	Processes are in place or evolving but do not lead to country-wide reimbursement	DHA "fast track" process launched, but no reimbursements made yet	DHA-specific reimbursement processes have been implemented

N.B. This is a qualitative assessment based on this research

CONCLUSION

- Digitalisation of healthcare is gathering pace everywhere with global reimbursement frameworks evolving to define funding standards for DHTs.
- Although the movements towards unification of assessment and funding for DHAs is seen in all countries in scope, only three have put in place a national, DHA-specific framework for funding and reimbursement.

Figure 3: Comparison of commercial opportunity with establishment of DHA reimbursement process

N.B. depends on robustness of the newly launched process in France and how successfully it will be implemented

Remap embecta ISPOR Boston US 7th – 10th May 2023 SCIENCEPOSTERS

[CLICK HERE TO VIEW ONLINE]

If you would like any further information on the plenaries or research presented below, please contact Paul or Graham at contact@remapconsulting.com

REMAP CONSULTING

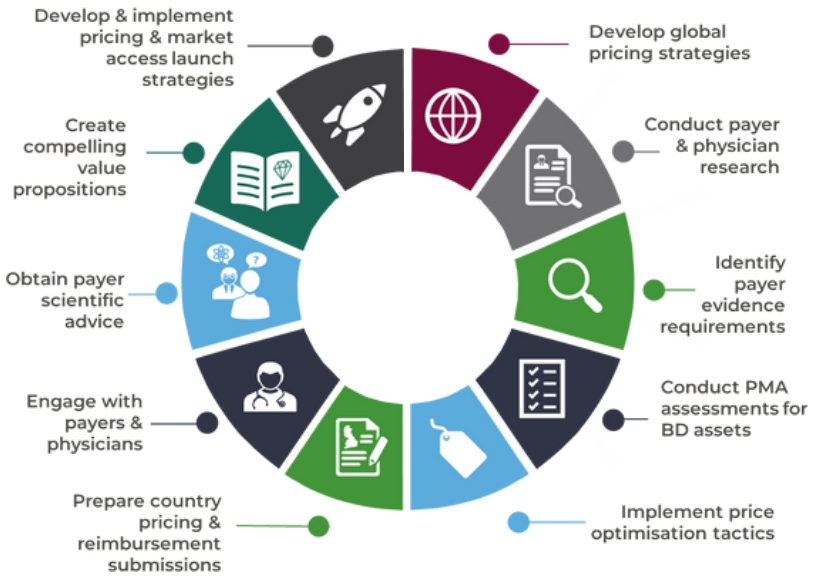
NAVGIATING MARKET ACCESS

Remap Consulting is a specialist pharmaceutical pricing, reimbursement and market access consultancy offering an integrated, evidence-based approach to optimising price and patient access for our client's products.

We work with a broad range of clients, from top 10 pharma through to small start-up organisations on a diverse range of business-critical projects, market access training and product launches.

Our mission is to help solve your pricing & market access challenges to enable improved patient access for your products.

Launch Strategy & Implementation



Price Optimization

Training

Flexible specialist training to upskill your team

- Bespoke training solutions specific to your needs and product pipeline
- Extensive range of off-the-shelf training modules from foundation to advanced market access learning including:

For more information on our services, please visit our website www.remapconsulting.com.

We always welcome your thoughts and opinions on the topics raised at ISPOR.

If you'd like to share anything or hear how we can support you in getting your product to market, email Paul and Graham, managing directors, today at: contact@remapconsulting.com.

Paul Craddy

MANAGING DIRECTOR
& FOUNDER

PAUL@REMAPCONSULTING.COM
+44 7957 028493

Graham Foxon

MANAGING DIRECTOR
& FOUNDER

GRAHAM@REMAPCONSULTING.COM
+44 7415 946778

Remap