Pioneering new frontiers in health economics and market access

ENVISION PHARMA GROUP

The presenters

Mel Formica

President, Value, Access and
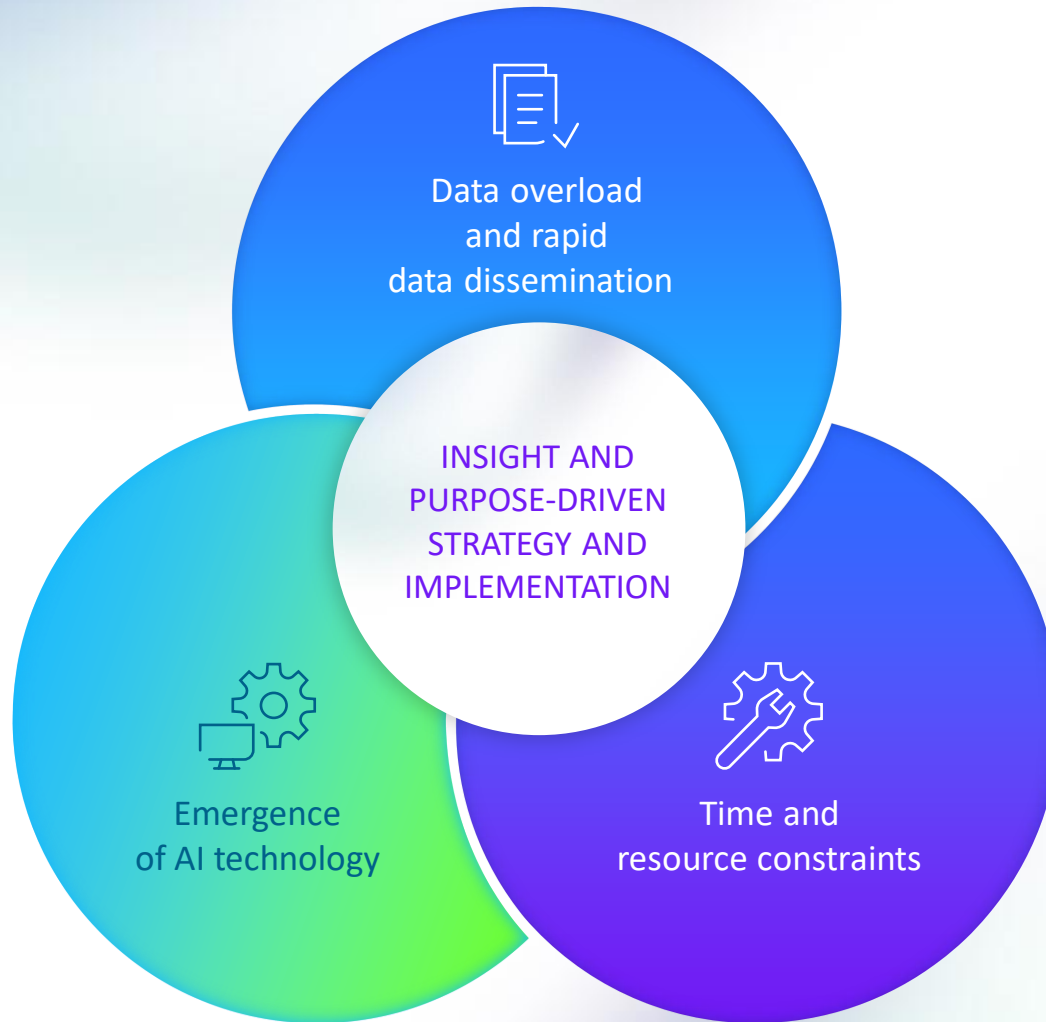Data Sciences

Suki Kandola

Global Head of
Integrated Solutions

Mike Glover

Global Head of Payer and
HTA Strategy

Stakeholder needs continue to evolve

REQUIRING SPONSORS TO EMBRACE VALUE-BASED HEALTHCARE
TO DRIVE IMPROVEMENTS IN POPULATION OUTCOMES

A company's need to collect the right evidence to demonstrate their asset's value to different stakeholders has never been stronger

Driving an evolution in regulatory, clinical, market access, medical (including health economic & outcomes research [HEOR]) and commercial strategies in clinical development

It is therefore an imperative that commercial and scientific capabilities be integrated to identify customer needs and design patient optimized assets

Envision's integrated evidence planning solutions

OFFER A **COMPREHENSIVE STRATEGY** FOR COLLECTING AND ANALYZING DATA THROUGHOUT THE ENTIRE PRODUCT DEVELOPMENT LIFE CYCLE

Demonstrates value ▷ Optimizes market access in an evolving landscape ▷ Incorporates patient-centered outcomes ▷ And a real world evidence strategy

Envision's integrated evidence planning solutions

OFFER A **COMPREHENSIVE STRATEGY** FOR COLLECTING AND ANALYZING DATA THROUGHOUT THE ENTIRE PRODUCT DEVELOPMENT LIFE CYCLE

Demonstrates value

Identifies and characterizes the patient population for which the drug is intended – understanding the epidemiology, unmet needs, treatment landscape, and patient preferences to develop a targeted value proposition

Demonstrates the product's safety, efficacy, and cost-effectiveness to support regulatory approval, reimbursement decisions, and market access strategies

Envision's integrated evidence planning solutions

OFFER A COMPREHENSIVE STRATEGY FOR COLLECTING AND ANALYZING DATA THROUGHOUT THE ENTIRE PRODUCT DEVELOPMENT LIFE CYCLE

Demonstrates value

▷

Optimizes market access

▷

Incorporates patient-centered outcomes

▷

And a real world evidence strategy

Envision's integrated evidence planning solutions

OFFER A COMPREHENSIVE STRATEGY FOR COLLECTING AND ANALYZING DATA THROUGHOUT THE ENTIRE PRODUCT DEVELOPMENT LIFE CYCLE

Optimizes market access

Identifies the needs of different stakeholders, such as HCPs, patients, healthcare providers, payers, regulators, to ensure data generated aligns to their value drivers, in an evolving market landscape

Leverages a cross-functional collaborative approach ensuring early alignment and helps bridge evidence gaps to demonstrate incremental value of the product to all the different stakeholders

Envision's integrated evidence planning solutions

OFFER A COMPREHENSIVE STRATEGY FOR COLLECTING AND ANALYZING DATA THROUGHOUT THE ENTIRE PRODUCT DEVELOPMENT LIFE CYCLE

Demonstrates value ▷ Optimizes market access ▷ Incorporates patient-centered outcomes ▷ And a real world evidence strategy

Envision's integrated evidence planning solutions

OFFER A **COMPREHENSIVE STRATEGY** FOR COLLECTING AND ANALYZING DATA THROUGHOUT THE ENTIRE PRODUCT DEVELOPMENT LIFE CYCLE

Incorporates patient-centered outcomes

Addresses real-world patients' needs by considering the patients' unmet needs, preferences, journey, etc., leading to faster adoption of the target population

Considers that many EU member states recognize the importance of patient engagement in HTA processes and have mechanisms to facilitate patient input at the advice and decision-making stages

Envision's integrated evidence planning solutions

OFFER A COMPREHENSIVE STRATEGY FOR COLLECTING AND ANALYZING DATA THROUGHOUT THE ENTIRE PRODUCT DEVELOPMENT LIFE CYCLE

Demonstrates value ▷ Optimizes market access ▷ Incorporates patient-centered outcomes ▷ And a real world evidence strategy

Envision's integrated evidence planning solutions

OFFER A COMPREHENSIVE STRATEGY FOR COLLECTING AND ANALYZING DATA THROUGHOUT THE ENTIRE PRODUCT DEVELOPMENT LIFE CYCLE

And a real world evidence strategy

To address unmet needs in the treatment landscape, and provide insights into how a drug performs in diverse patient populations, with varying disease severity and comorbidities
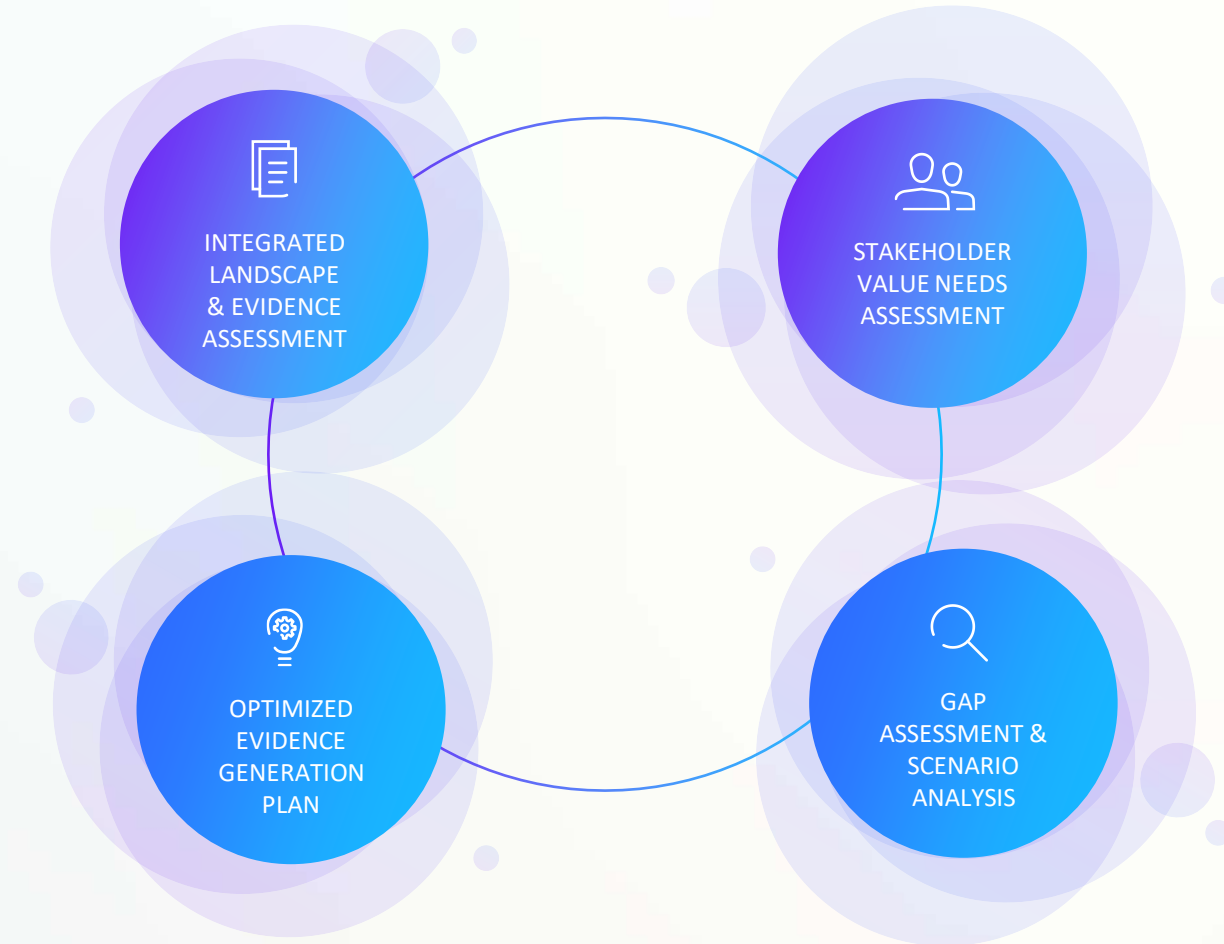
Leverage RWE to make HTA submissions more robust, fill gaps where RCT data is limited, assess comparative effectiveness, or to demonstrate the long-term value of the product

Envision's integrated evidence planning solutions

MAXIMIZE ASSET VALUE BY UTILIZING AI/ML TECHNOLOGY

Envision's integrated evidence planning solutions

MAXIMIZE ASSET VALUE BY UTILIZING AI/ML TECHNOLOGY

DATA MANAGEMENT AND INTEGRATION helps integrate and manage large volumes of data from disparate sources, such as electronic health records, claims data, and patient-reported outcomes, by identifying relevant variables, cleaning data, and handling missing values

NATURAL LANGUAGE PROCESSING (NLP) – to extract information from unstructured data sources like clinical notes, social media, or patient forums, providing valuable insights into patient experiences, preferences, and outcomes

AI-DRIVEN PREDICTIVE ANALYTICS can help identify patterns and trends in data, to better understand disease progression, treatment response, and risk factors, and to anticipate future outcomes

MACHINE LEARNING AND DEEP LEARNING ALGORITHMS can analyze complex, high-dimensional data, uncovering relationships between variables and improving the accuracy and efficiency of outcomes research

PATIENT STRATIFICATION – identification of patient subgroups that have different treatment responses or outcomes, enabling more targeted approaches to care

HEALTH ECONOMIC EVALUATIONS can enhance cost-effectiveness and budget impact analyses, providing more accurate and timely information on the value of interventions

CONTINUOUS LEARNING AND ADAPTATION – AI systems can continuously learn from new data and evidence, enabling IEPs to be updated and refined over time, ensuring that they remain relevant and useful for decision-making
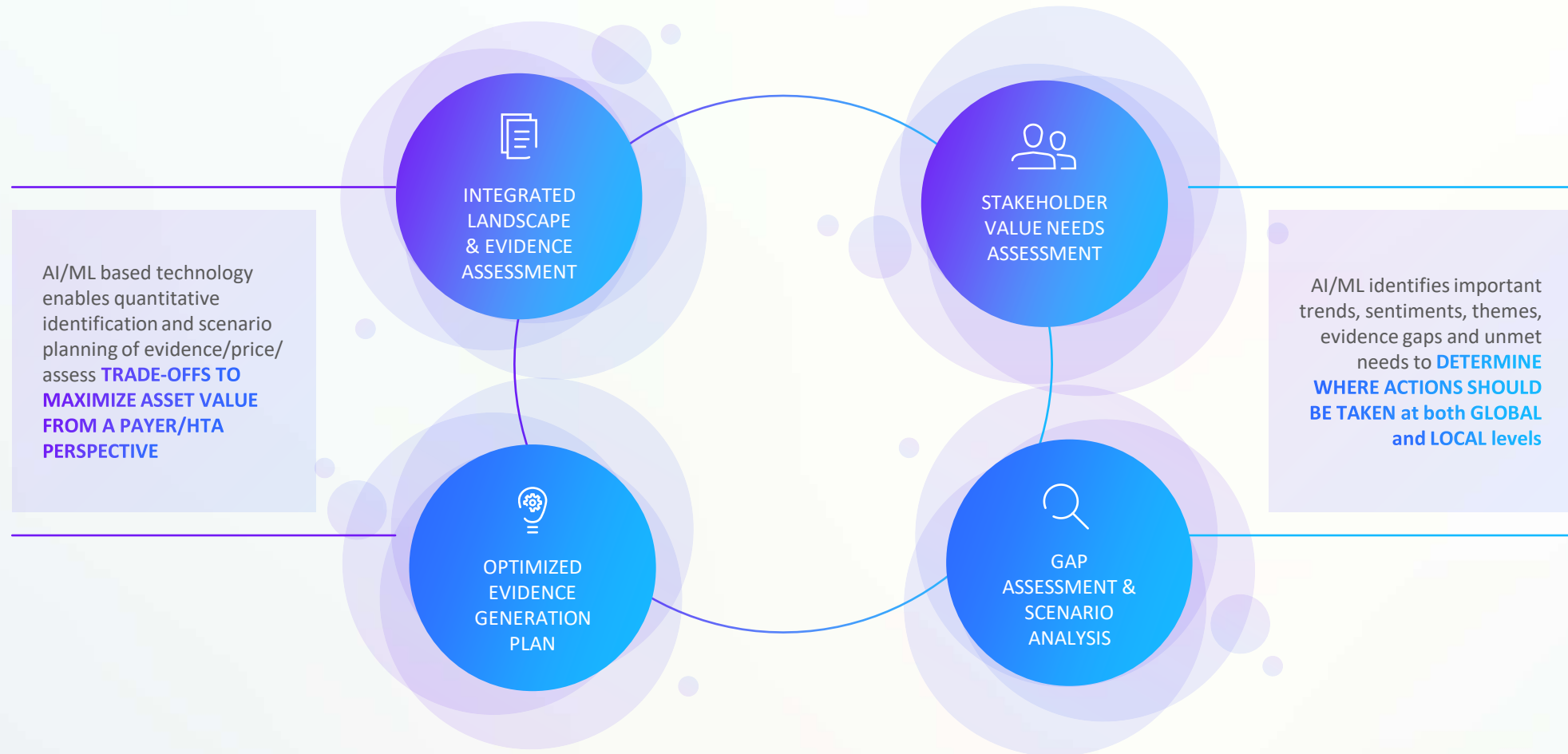
By leveraging AI in the development and implementation of IEPs, we gain more accurate, efficient, and actionable insights into the value of healthcare interventions, ultimately leading to improved patient care and health outcomes

Envision's integrated evidence planning solutions
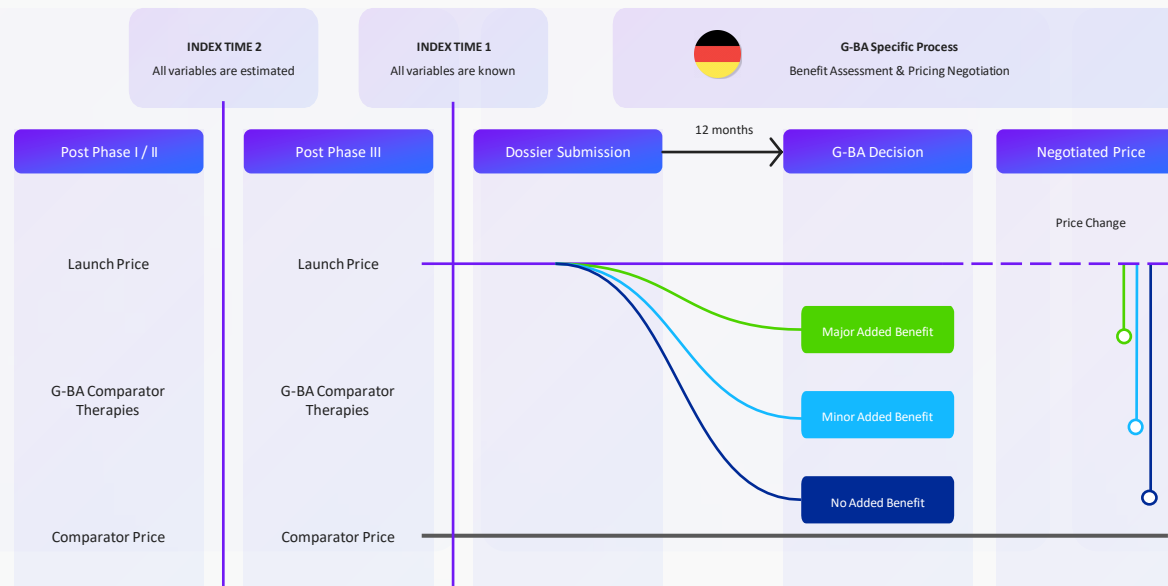
MAXIMIZE ASSET VALUE BY UTILIZING AI/ML TECHNOLOGY

AI/ML based technology enables quantitative identification and scenario planning of evidence/price/ assess **TRADE-OFFS TO MAXIMIZE ASSET VALUE FROM A PAYER/HTA PERSPECTIVE**

INTEGRATED LANDSCAPE & EVIDENCE ASSESSMENT

STAKEHOLDER VALUE NEEDS ASSESSMENT

OPTIMIZED EVIDENCE GENERATION PLAN

GAP ASSESSMENT & SCENARIO ANALYSIS

AI/ML identifies important trends, sentiments, themes, evidence gaps and unmet needs to **DETERMINE WHERE ACTIONS SHOULD BE TAKEN at both GLOBAL and LOCAL levels**

Evidence generated through the IEGP is used to support a product's value proposition

AND INFORM PRICING AND REIMBURSEMENT DECISIONS

AI PRICING MODEL ALIGNED WITH HTA PROCESS

INDEX TIME 2
All variables are estimated

INDEX TIME 1
All variables are known

G-BA Specific Process
Benefit Assessment & Pricing Negotiation

Post Phase I / II

Post Phase III

Dossier Submission

12 months

G-BA Decision

Negotiated Price

Price Change

Launch Price

Launch Price

Major Added Benefit

Minor Added Benefit

No Added Benefit

G-BA Comparator Therapies

G-BA Comparator Therapies

Comparator Price

Comparator Price

Simulating a real-world scenario during the model training and testing

80%   20%

TRAINING SET   TEST SET

Envision's integrated evidence planning solutions

OFFER A **COMPREHENSIVE STRATEGY** FOR COLLECTING AND ANALYZING DATA THROUGHOUT THE ENTIRE PRODUCT DEVELOPMENT LIFE CYCLE

Demonstrates value ▷ Optimizes market access ▷ Incorporates patient-centered outcomes ▷ And a real world evidence strategy

RWE is increasingly playing a critical role in evidence demonstration and access strategies

SUPPORT REGULATORY AND HTA APPROVAL

- Identifying mechanisms of missing data

- Demonstrating how the data can be structured to provide a better understanding of the target population

- Establishing a mechanism to supplement and enrich randomized clinical trials and other observational studies in various countries

INFORM CLINICAL PRACTICE

- Providing insights into the effectiveness of the product in real-world settings

- Supporting shared decision-making between patients and healthcare providers

- Identifying opportunities to improve patient outcomes
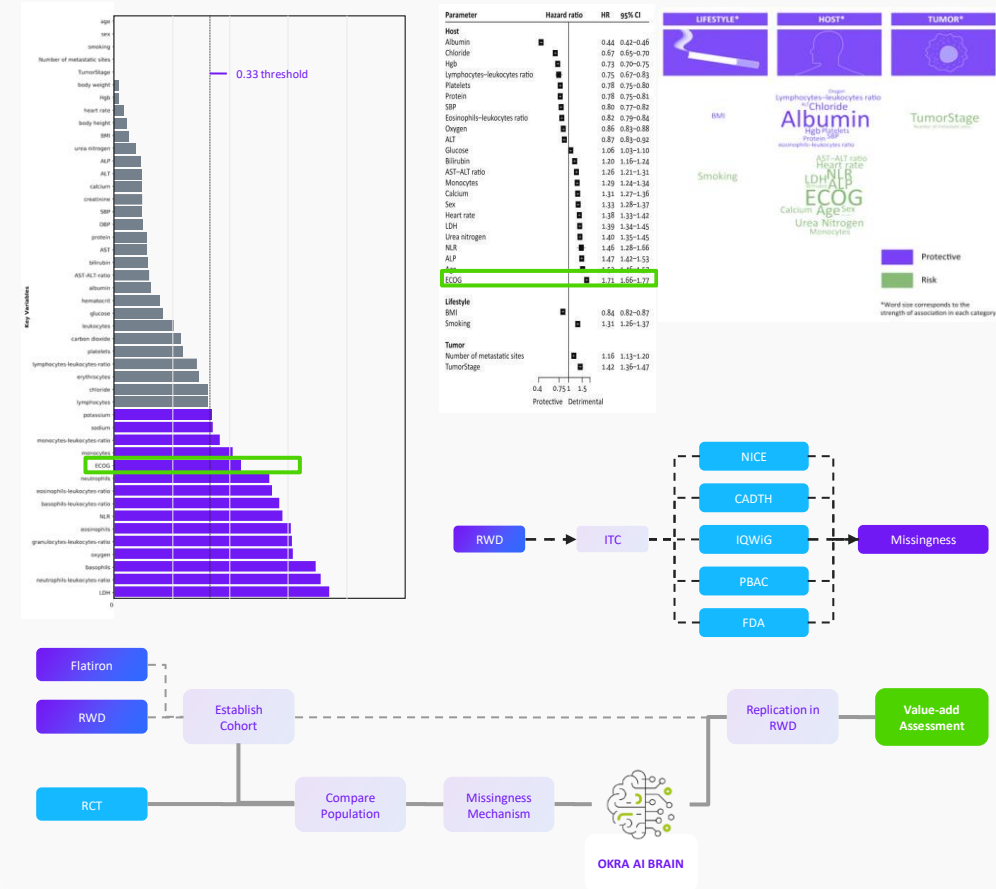
RWE can help to generate a comprehensive and robust evidence base that supports the product's value proposition

IDENTIFYING UNMET NEEDS

- Demonstrate how new treatments are likely to alleviate societal burden for patients and their caregivers

- Identify unmet medical needs or areas of clinical practice that are not well understood

- Reliably estimate potential burden on caregivers and the society

DEMONSTRATING VALUE

- Deliver information on product efficiencies and optimal patient treatment plans

- Provide critical insights to therapy's safety, efficacy, and cost-effectiveness in routine clinical practice

- Inform clinical practice and reimbursement guidelines
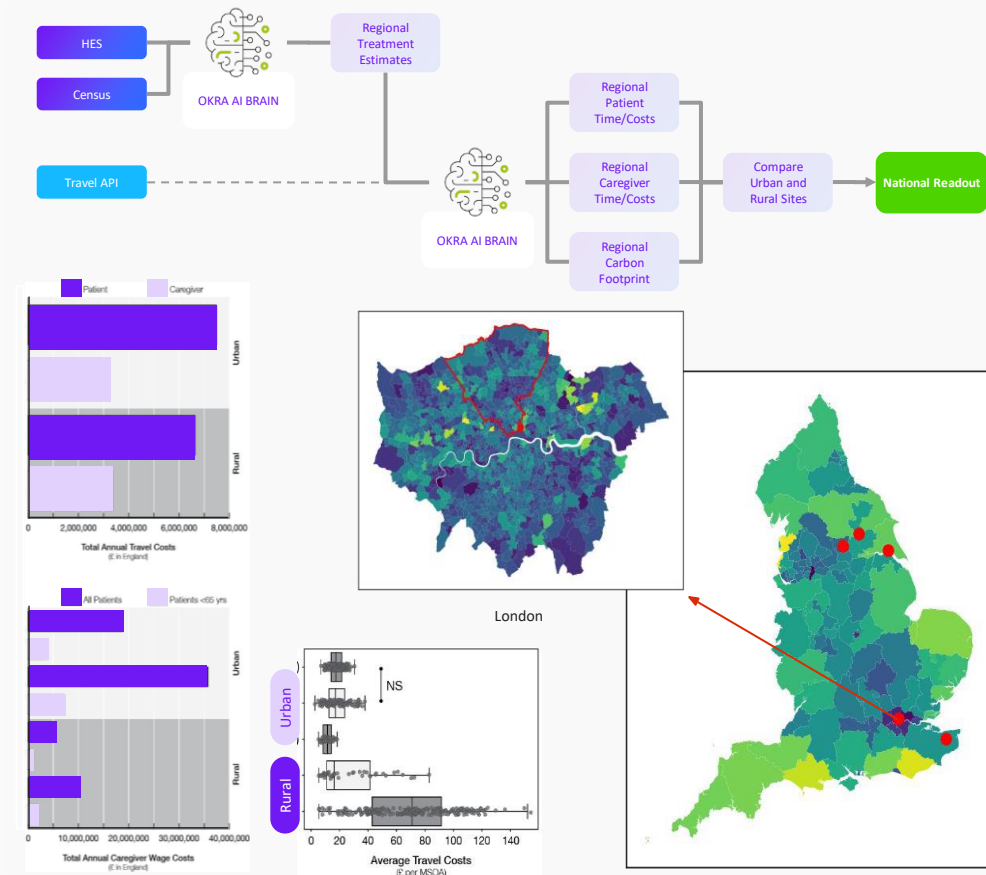
Thank you

ENVISION PHARMA
GROUP
Driven by evidence, enabled by technology