Patient Data Applications Across Product Lifecycle

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SRI Strategic Research Insights

pmsa

PHARMACEUTICAL MANAGEMENT
SCIENCE ASSOCIATION

Presenters of this Webinar

Harshad Chiddarwar, Director, SRI

- 10+ years experience in pharmaceutical consulting across secondary data analytics and market research
- Experience in neurology, oncology, virology, respiratory, migraine, diabetes, women's health, and GI
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- 15+ Years' experience Life Science Industry
- Account management, business development, marketing and product development expertise
- BS Biochemistry, UCLA

Who is SRI?

Four Core Practice Areas

Qualitative Research

Big Data Analytics

Quantitative Primary Research

C-Suite Consulting

Concentration in pharma / biotech / healthcare industry with US & Global Reach

Experienced professionals with advanced degrees in marketing / market research / operations research / statistics

Contents

What is Patient Level Data?

Phases of Drug Lifecycle

Applications of Patient Level Data in Each Phase

Application in Pre-commercial Stage: Case Study

Applications in Commercial Stage: Case Study

Q&A

What is Patient Level Data (PLD)?

Types of Patient Level Data

Claims Data

Lab Data

EMR / EHR Data

Publicly Available Patient Registry

Patient Digital Data
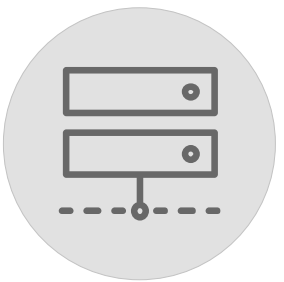
Patient Services HUB

Specialty Pharmacy & GPO Data

Patient Level Data

Claims Data - Patient Transactions

Demographics   Appointments   Diagnoses   Medications   Procedures   Billing   Insurance

ADVANTAGES

❖ Direct from source of the transactions
  - Pharmacy
  - Insurance

❖ Large sample size
  - Analyze rare medical conditions

CHALLENGES

❖ Blindspot - cash payment (lack of insurance)
❖ Over-the-counter medications
❖ Coverage varies by market and geography
❖ Limited information regarding outcome

Patient Level Data

Lab Data - Patient Sample Results

Demographics

Lab Results

ADVANTAGES

❖ Precise and detailed lab outcomes
❖ Large sample size

CHALLENGES

❖ Coverage varies by market and geography
❖ Unavailable for certain medical conditions

Patient Level Data

EMR Data - Digital Medical and Treatment History Over Time

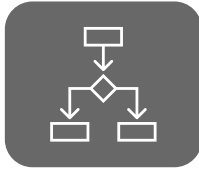| Demographics | History | Diagnoses | Medications | Procedures | Lab Results | Notes | Outcome |

ADVANTAGES

- ❖ Comprehensive Patient Journey
- ❖ Detailed HCP Documentation
- ❖ Longitudinal Data

CHALLENGES

- ❖ Lack of Interoperability
- ❖ Data Access
- ❖ Small Subset of Patients
  - • Depends on the Therapy Area
  - • Extrapolations Might Not Always Work

Phases of Drug Lifecycle

Phases of Drug Lifecycle

Pre-Commercial

Pre-Clinical

Clinical Phases

Commercial: Launch

Commercial: Growth

Commercial: Maturity

Commercial: Loss of Exclusivity
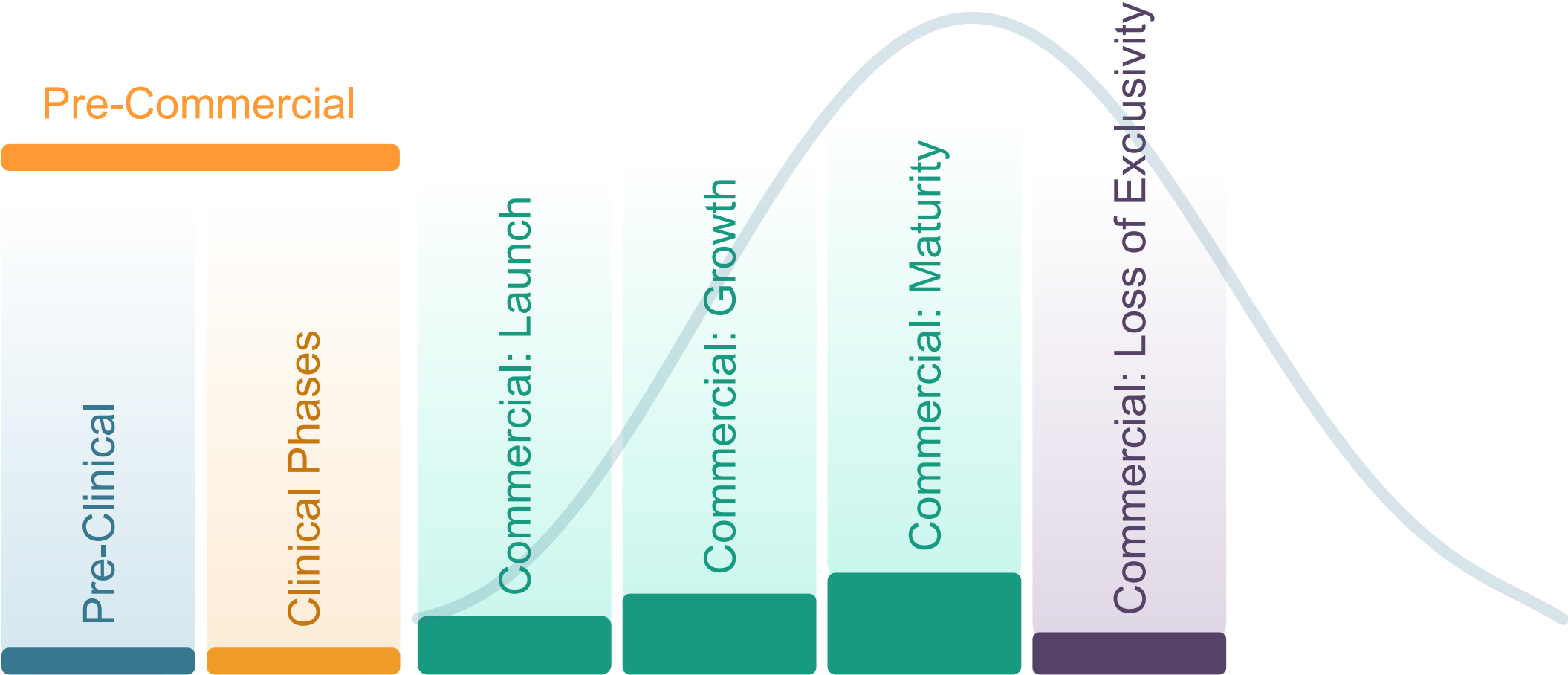
Application of PLD Across Phases of Drug Lifecycle

Pre-commercial

Business Questions

In this phase, a pharma company tries to understand current market landscape, and answer key business questions:

- Which specialties treat the most in the market?

- How do patients move through various specialties?

- What treatments are currently available in the market?

- At what stage in treatment algorithm can the product be used?

- How many patients are still uncontrolled? What is the market size?

Pre-commercial

Business Questions

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- How do patients move through various specialties?

- What treatments are currently available in the market?

- At what stage in treatment algorithm can the product be used?

- How many patients are still uncontrolled? What is the market size?

Direct Applications of Patient Level Data
Forecasting and Projections
Market Sizing / Landscape
Market Product Mix
Product Placement
Clinical Trial Recruitment

Hybrid Analytics with Market Research
Facilitate Study Recruitment
Triangulate MR Findings with HCP Behavior
Demand Estimation

Commercial: Launch

Business Questions

In this phase, a pharma company's focus is to establish market share, and tries to answer key questions such as:

- Which HCPs are Early Adopters of new products?
- Which HCPs are Key Opinion Leaders?
- Which HCPs should be targeting focus at launch?
- What messages are resonating with the HCPs?
- What are some of the key HCP attitudes towards the product?
- Which payors should be contracted with?

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Commercial: Launch

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- What messages are resonating with the HCPs?
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- Which payors should be contracted with?

Direct Applications of Patient Level Data
Forecasting and Projections
Market Access - Payor Contracting Strategy
HCP Adoption
HCP Behavioral Segmentation
HCP Targeting
Post-launch Tracking
Patient Segmentation
Patient Identification

Hybrid Analytics with Market Research
Attitudinal Segmentation
Message Recall Studies
ATU Studies

Commercial: Growth

Business Questions

In this phase, the company's focus is to drive repeat prescriptions and continue driving adoption. Key questions answered:

- Which HCPs are Late Adopters of new products?

- What type of HCPs have adopted the product thus far?

- Which payors should be contracted with?

- How well are payors adhering to the contract?

- Have the HCPs attitudes towards the product changed?

- What messages are resonating with HCPs?

Commercial: Growth

Business Questions

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- Which HCPs are Late Adopters of new products?
- What type of HCPs have adopted the product thus far?
- Which payors should be contracted with?

- How well are payors adhering to the contract?
- Have the HCPs attitudes towards the product changed?
- What messages are resonating with HCPs?

Direct Applications of Patient Level Data
Market Access - Payor Contracting Strategy
HCP Utilization
Identify Market Gaps
Sales Force Effectiveness
HCP Targeting
Cost Sensitivity Analysis

Hybrid Analytics with Market Research
ATU Studies
Message Recall Studies
Attitudinal Segmentation
Hybrid Segmentation

Commercial: Maturity

Business Questions

In this phase, the company's primary focus is to maintain market share, establish HCP / Patient loyalty, and defend against new entrants. Some of the key questions answered in this phase are:

- What would be the impact of new entrants in the market?

- What patient segments are underserved?

- Are HCPs habituated to following a certain treatment algorithm?

- How best to allocate marketing budgets across channels?

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Commercial: Maturity

Business Questions

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- What patient segments are underserved?

- Are HCPs habituated to following a certain treatment algorithm?
- How best to allocate marketing budgets across channels?

Direct Applications of Patient Level Data
Market Access (Payor Dynamics)
Referral Patterns
Identify New Market Segments
HCP Messaging
Sales Force Effectiveness
Cross Channel Spillover

Hybrid Analytics with Market Research
Behavioral Economics / Habit Studies?
Marketing Mix
Demand Estimation

Commercial: Loss of Exclusivity

Business Questions

In this phase, the company typically focuses on identifying new competitive market segments within the same indication, and find new indications to be approved for. Some of the key questions answered in this phase are:

- What patient segments are underserved?

- What is the market size of underserved patient segment?

- What is the market size for new potential indication?

- What is the forecast for the new indication?

Commercial: Loss of Exclusivity

Business Questions

In this phase, the company typically focuses on identifying new competitive market segments within the same indication, and find new indications to be approved for. Some of the key questions answered in this phase are:

- What patient segments are underserved?

- What is the market size of underserved patient segment?

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- What is the forecast for the new indication?

Direct Applications of Patient Level Data
Identify Competitive Markets
Detailed Physician Segmentation
Forecasting and Projections
Cost Sensitivity Analysis

Case Study

Application of PLD in Pre-commercial Phase

Goals For Pre-Commercial APLD Analysis

Elucidate the "Patient Journey"

Scope Product Opportunity

Refine Product Positioning

Establish (Defensible) Benchmarks

Revenue Model Architecture & Variables

Robust Data Set

Business Questions (Subset)

Pretreatment indicators for a specific class

Prevalence by disease severity

01

06

02

Market Definition & Communication Pillars

Role of HCPs by specialty

Sequencing Therapy

05

03

HCP adherence to guidelines

04

Referral Patterns
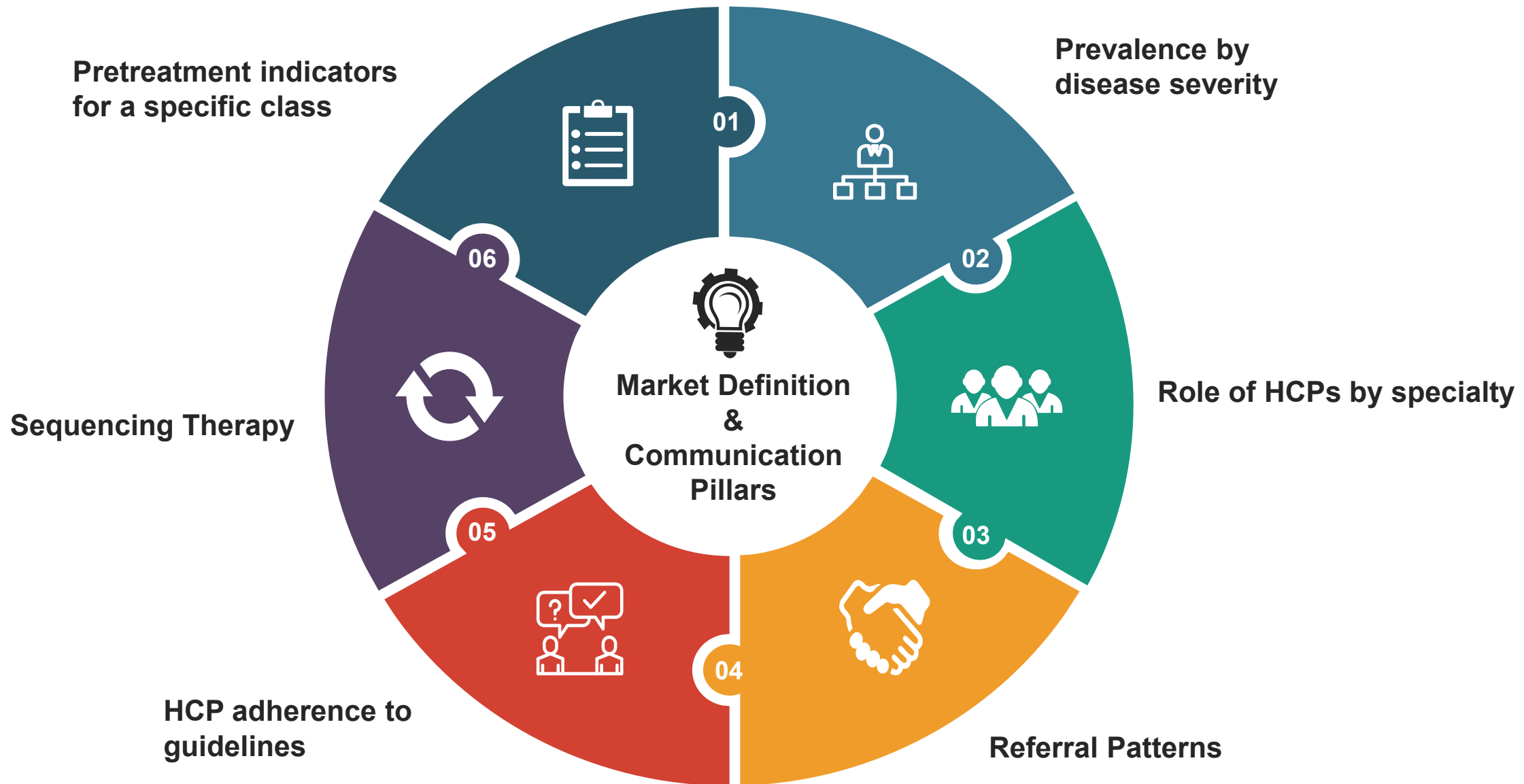
Prevalence by Disease Severity

Distribution of Patients in Each GINA Step
(Adult Asthma Patients Classified According to GINA 2019 Criteria, n=2,065,759)
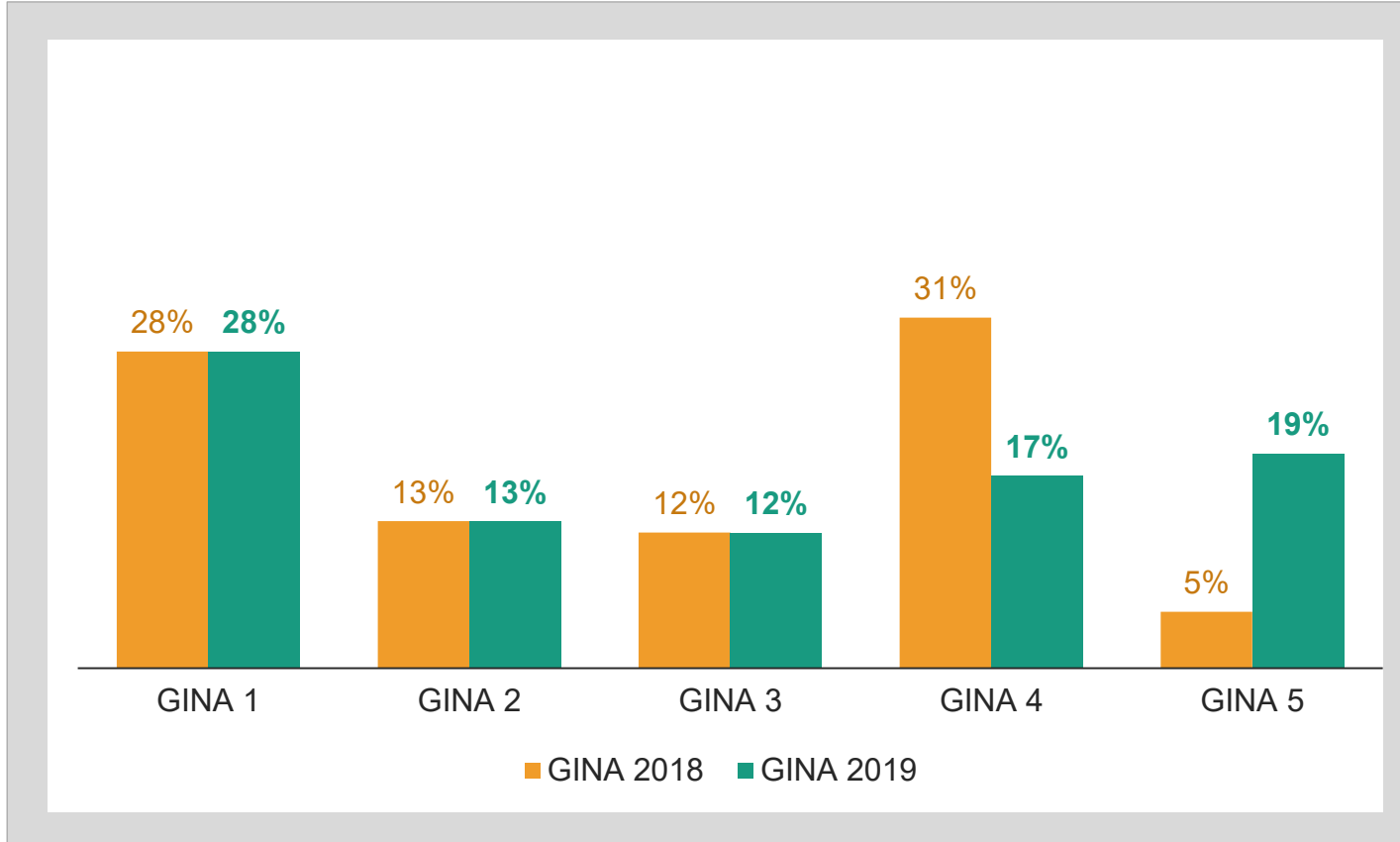
Triangulate and **refine** estimates for eligible population and product positioning to inform:

- Patient segmentation/stratification
- Value proposition
- Market access drivers/barriers
- Market opportunity
- Product valuation

Source" Symphony claims data, 10/31/2013 – 10/31/2018; subjects in the analysis were adults (age ≥ 18 years) who had ≥ 2 claims indicating asthma on separate dates during a 24-month window, and able to be classified by GINA 2019 step

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Physician Roles & Referral Patterns

Dimensionalize patient management across healthcare providers

- Further elucidate market access barriers & identify "outliers" to the norm
- Identify opportunities for engagement
- Inform go-to-market strategies/strategy
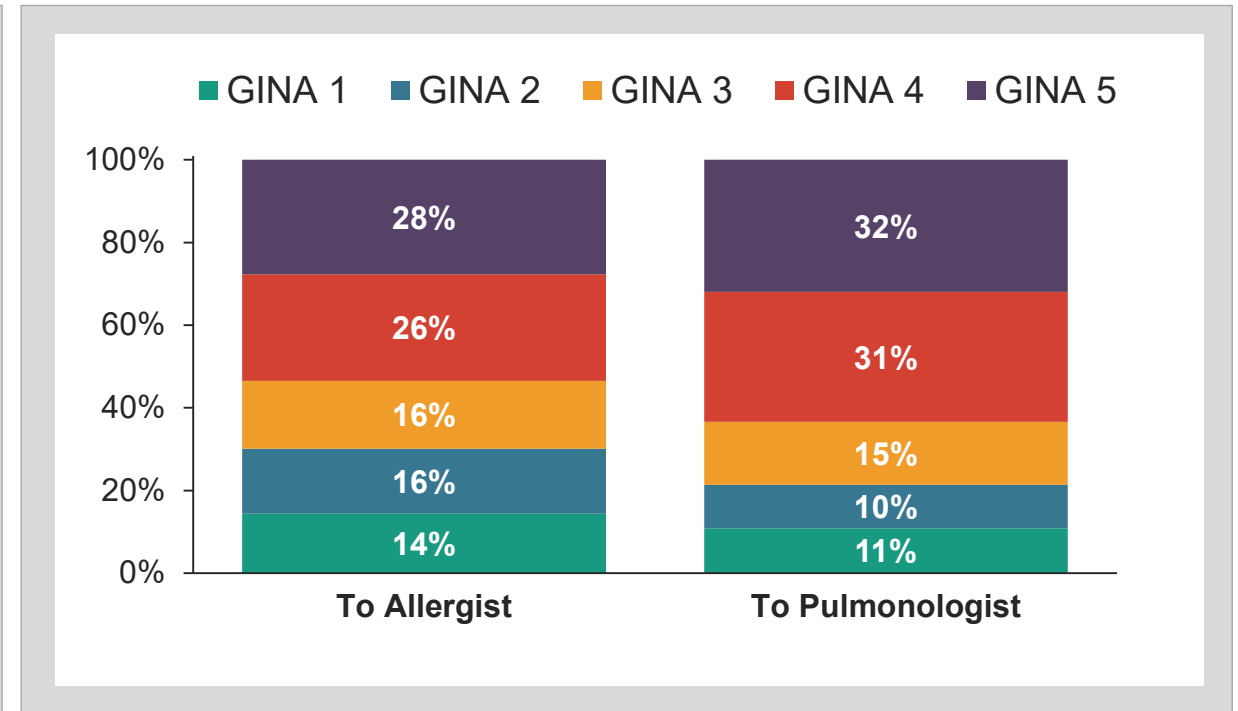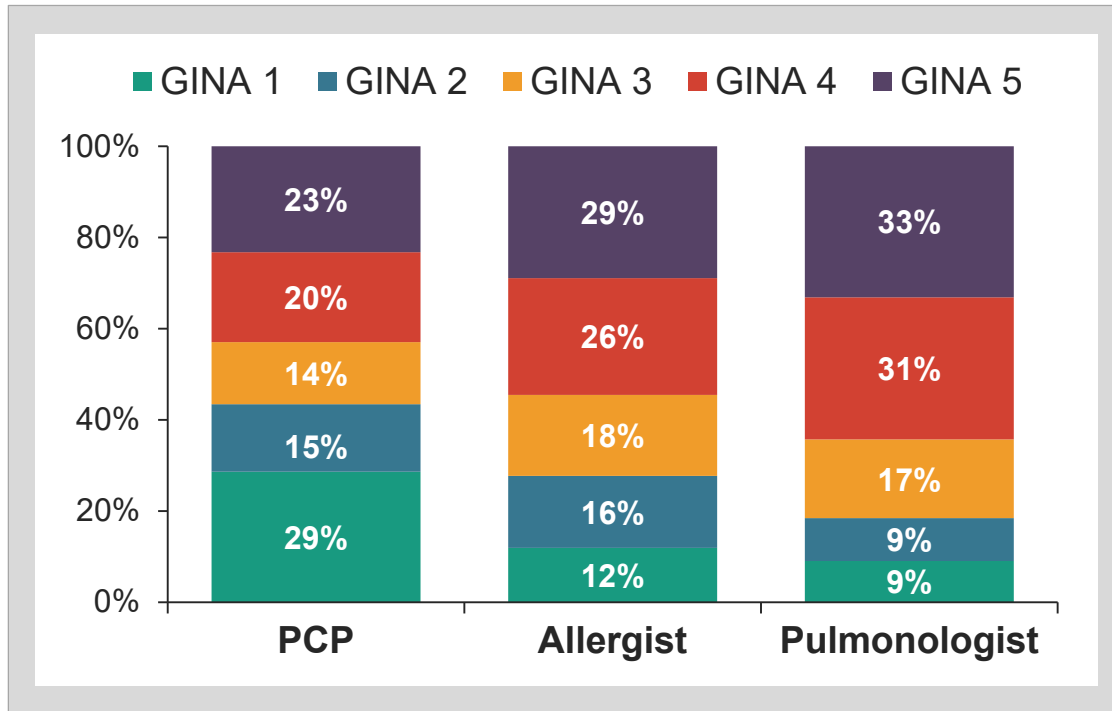
Impact of Changes in the 2019 GINA Treatment Classification: Assessment in a Real-world Setting

P0019

Fernando Holguin[1], Carlos A. Camargo, Jr[2], William Busse[3], Nicola A. Hanania[4], Emily Pennington[5], Harshad Chiddarwar[6], Gina Nelson[7], Hector Ortega[7]

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INTRODUCTION

- 2019 Global Initiative for Asthma (GINA) recommendations state that patients requiring high-dose inhaled corticosteroids (ICS) plus a long-acting β-agonist (LABA) are uniquely assigned to Step 5[1]

- Previously this Step included patients requiring medium- and high-dose ICS combination treatments

- Limited data exist that describe the impact of these changes across GINA Steps. Here we aimed to assess the effects of GINA 2019 updates in a real-world setting

METHODS

- Retrospective analysis based on medical claims data acquired from Symphony Health, between October 2013 and October 2018

- Patients included in this analysis:
  - Age ≥ 18 years
  - ≥ 2 separate claims indicating asthma
  - 2 years of active enrollment prior to index date
  - Classified by GINA 2018 and GINA 2019 criteria

- Endpoints:
  - Shift in GINA Step assignment with 2019 update
  - GINA assignment by healthcare provider (HCP) specialty, including primary care physicians (PCPs), allergists, and pulmonologists

RESULTS

- From a total sample of ~4.2 million patients, 2,286,847 met the criteria for this analysis

RESULTS

- Using GINA 2018 criteria, 28%, 13%, 12%, 31%, and 5% of patients were assigned to GINA Steps 1, 2, 3, 4, and 5, respectively (**Figure 1**)

- When GINA 2019 criteria were applied (still classifying patients on short-acting β-agonist only as GINA 1), 28%, 13%, 12%, 17%, and 19%, were classified as GINA Steps 1, 2, 3, 4, and 5, respectively (**Figure 1**)

- Approximately 10% of patients (not shown) were unable to be classified according to GINA criteria

Figure 1. Distribution of Asthma Patients by GINA 2018 and GINA 2019

N = 2,286,847 (n = 2,065,759 able to be classified)
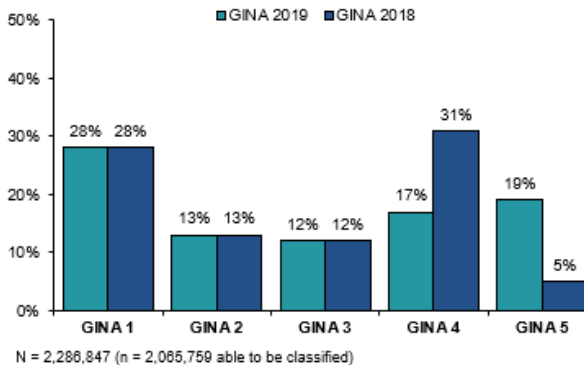
Data were further evaluated by HCP specialty:

- GINA Step 5 patients accounted for 6% and 23% of PCPs' asthma populations in 2018 (**Figure 2A**) and 2019 (**Figure 2B**), respectively

- This change was consistent with the shift in the overall population, irrespective of provider

- Similarly, among allergists and pulmonologists, the proportion of GINA Step 5 patients increased from 10% to 29%, and 14% to 33%, respectively

- Among all HCPs, GINA 2019 changes resulted in about 2- to 4-fold increase in patients classified in the highest severity category (GINA Step 5)

Figure 2. GINA Step by HCP Specialty by A. 2018 and B. 2019 recommendations (N = 2,065,759)

- At the time of referral to a specialist, over half of patients were at GINA Step 4 or 5 with a higher proportion of patients referred to a pulmonologist (**Figure 3**)

- Roughly one quarter were referred at GINA Steps 1 or 2, and a minority (10%) receive no treatment prior to referral
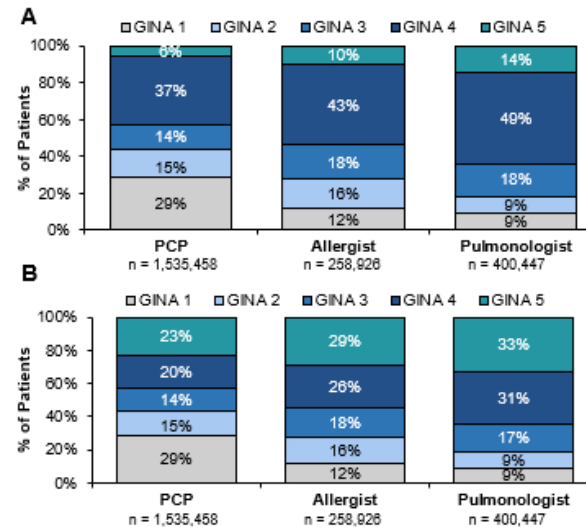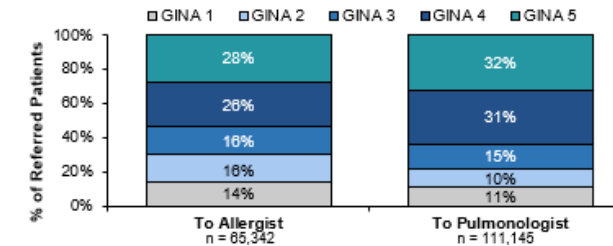
Figure 3. GINA Step at referral (n = 167,592)

CONCLUSIONS

- Two thirds of patients retained the same GINA Step assignment across GINA 2018 and 2019 classifications

- One third of patients moved to a different Step when applying GINA 2019; nearly half classified as Step 4 by 2018 criteria (high-dose ICS/LABA) moved to Step 5 when 2019 criteria were applied

- Based on GINA recommendations, patients with severe disease (GINA 4-5) are more frequently referred to a specialist. Notably, approximately 20-30% are referred with "mild" disease (GINA 1-2).

- Early adoption of these revised GINA recommendations may provide better understanding of disease severity and related management across health care providers

REFERENCES

1. Global Initiative for Asthma. Global Strategy for Asthma management and Prevention, 2019. Available at: www.ginasthma.org

ACKNOWLEDGEMENTS

Critical Success Factors

Cross-functional collaboration

Clear **understanding** of what types of **business questions** an APLD analysis could answer

Internal **champion**

Integrate with other data

Clarity as to what **questions** an **APLD** analysis could *not* answer

Defined **quality control** process with checks & balances

Plan, including **defined business rules**
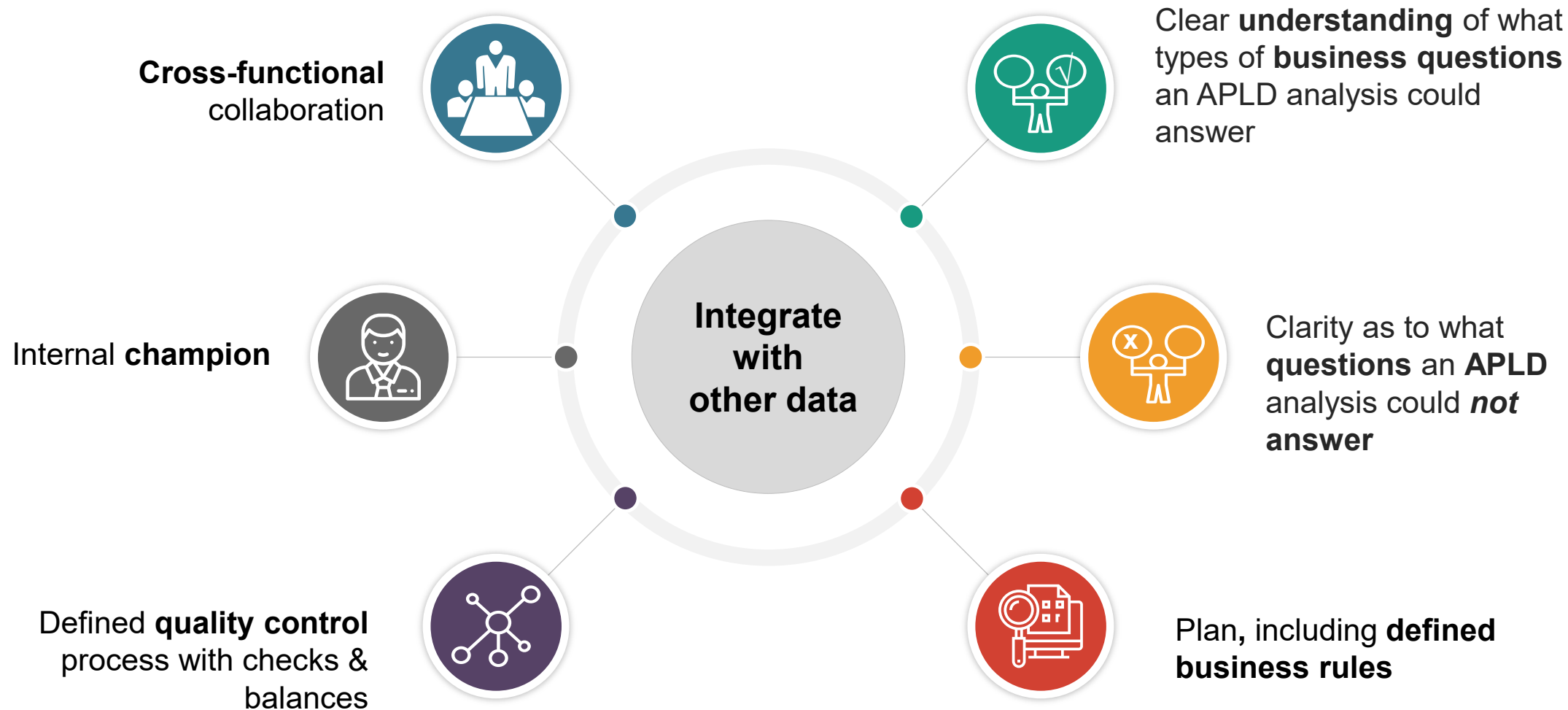
Case Study

Application of PLD in Commercial Phase

Utilize Real World Evidence to Predict Cancer Type and Stage
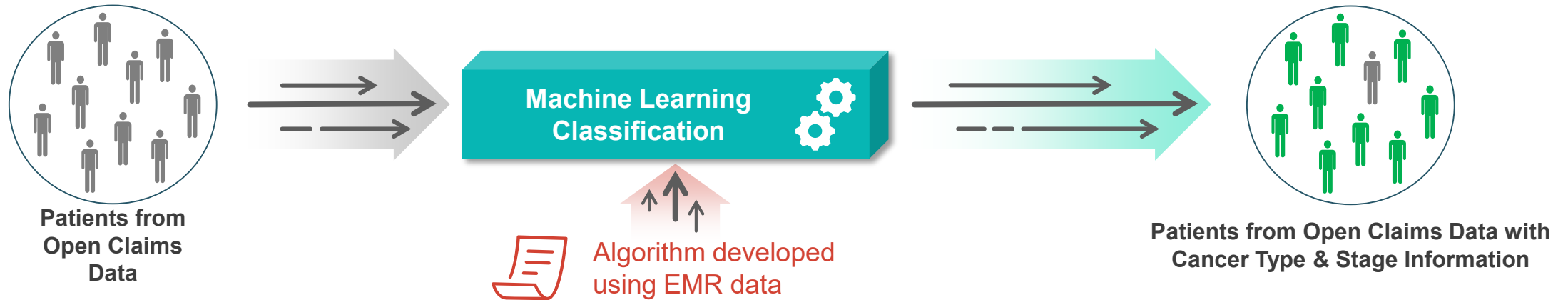
The client team was launching a new agent to treat a specific late-stage brain cancer condition. For commercial success, the client team wanted to understand what proportion of patients have progressed to the late-stage brain cancer condition

The requirement was challenging because the ICD codes only provide information on location of the cancer, and no information on type or severity of the cancer

The client team had procured industry standard open claims data, along with EMR data to estimate commercial opportunity

Utilize Real World Evidence to Predict Cancer Type and Stage

Patients from Open Claims Data

Machine Learning Classification

Algorithm developed using EMR data

Patients from Open Claims Data with Cancer Type & Stage Information

Using EMR data, **SRI identified specific treatment regimen** that are used to treat patients with specific cancer type at specific stage

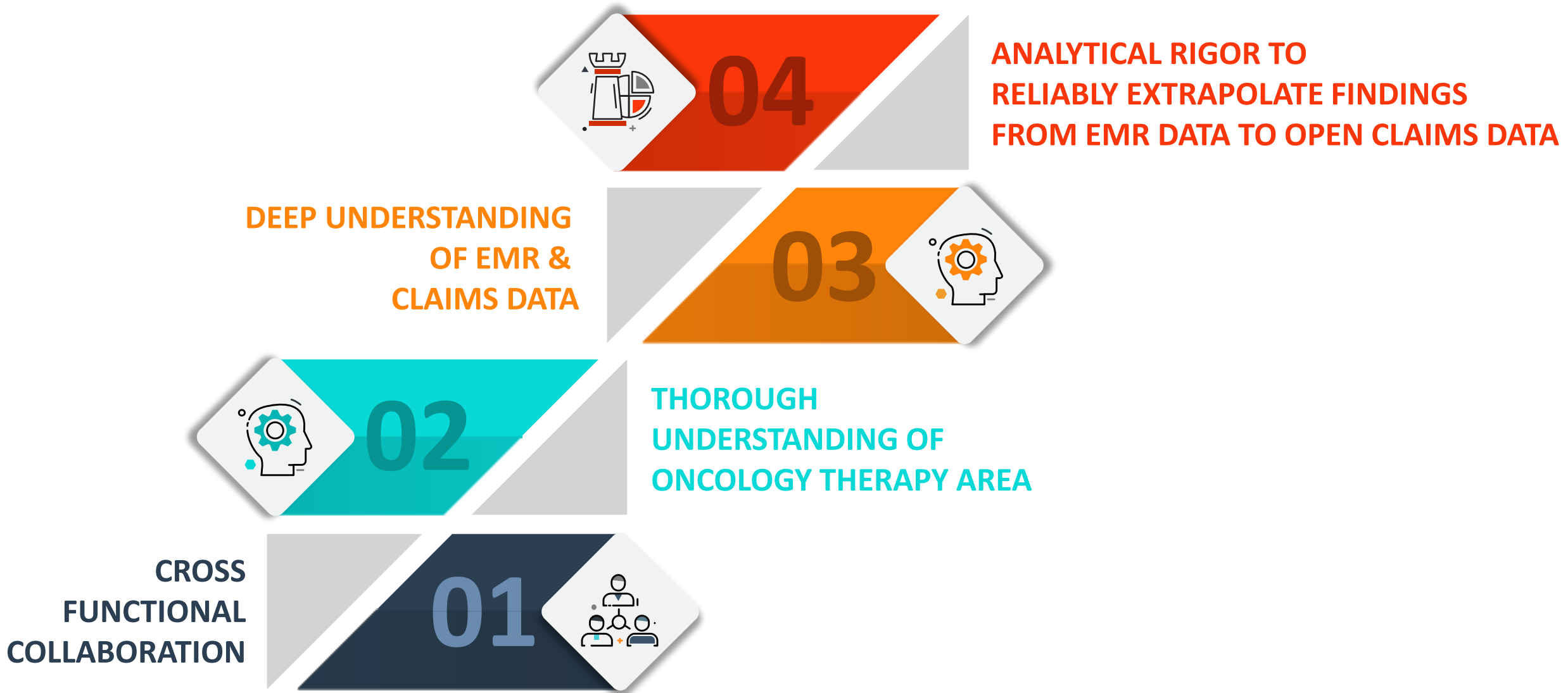The regimen to cancer type and stage mapping was **validated by the HEOR** team

EMR rules were **overlayed on** patient level **open claims data** to identify patients that could benefit from the client's product

The finalized algorithm had **90% accuracy** in identifying beneficiary patients over a large patient pool

Success Factors

04 ANALYTICAL RIGOR TO RELIABLY EXTRAPOLATE FINDINGS FROM EMR DATA TO OPEN CLAIMS DATA

DEEP UNDERSTANDING OF EMR & CLAIMS DATA **03**

02 THOROUGH UNDERSTANDING OF ONCOLOGY THERAPY AREA

CROSS FUNCTIONAL COLLABORATION **01**

Q&A