# PHARMA MARKETING: UNRAVEL RWD WITH ADVANCED ANALYTICAL FRAMEWORKS TO STRATEGICALLY PREPARE FOR COMMERCIAL BIOSIMILAR LAUNCH

JAN 2021

# MEET THE TEAM

## JANANI DAMODARAN

### CONSULTANT

Janani is Consultant at D Cube Analytics; she comes with 6+ years of experience in supporting Market Planning and Brand teams with analytical solutions to make strategic data driven decisions. She has extensively worked on Oncology, Neuro and Immunology therapeutic areas covering a spectrum of business problems - Pre/Post Drug Launch Strategic Analysis, Patient Chart Audits, Physician-level data analytics, Sales Force Effectiveness and Primary Market Research

## DANIEL BRITTO

### ASSOCIATE CONSULTANT

Daniel is an Associate Consultant at D Cube Analytics, who has around 5+ years of experience in supporting the analytical needs of the regional and global brand teams in their quest towards building-up next-gen strategies across launch and pre-launch space. He brings in expertise on the Inflammation therapeutic area and has solved business problems pertaining to sales and commercial analytics, Payer and Provider analytics, and also Patient treatment dynamics by leveraging syndicated data sources and extensive market research

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# OVERVIEW OF BIOSIMILARS

**Biosimilars**

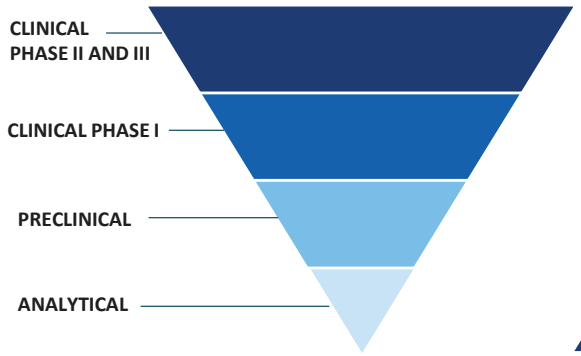
- A biosimilar is a biologic that is highly similar to and has no clinically meaningful differences (in terms of quality, safety and efficacy) from another biologic that's already approved and whose patent has expired, known as a reference product
- Minor differences between the reference product and the proposed biosimilar in clinically inactive components are acceptable

## How are biosimilars different from their reference product?

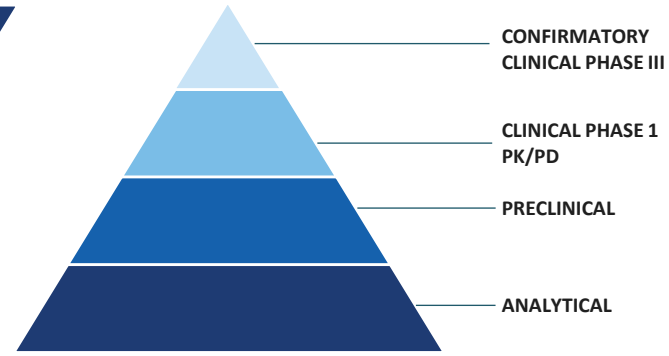
| | Biologic | Biosimilar | Generics |
|---|---|---|---|
| Definition | Reference product | Similar to, and not identical to reference product | Bioequivalent and identical to reference product(non-biologic) |
| Development Cost | $800 Million - $1 Billion | $100 – $200 Million | $1 – $2 Million |
| Time to Market | 15 years | 8 – 10 years | 2 – 3 years |
| Launch price | Most expensive | 20-30% discount over reference product | 80-90% discount over reference product |

## FDA Approval Pathway

Approval of a biosimilar is based on the "totality of the evidence" standard, which can be defined as the sum of data from analytical, preclinical, and clinical studies




**REFERENCE MEDICINE DEVELOPMENT**
Main goal is to determine the clinical effect for each indication




**BIOSIMILAR DEVELOPMENT**
Main goal is to establish similarity to the reference medicine



***Please note:*** *Facts represented in the slides are referred from verified & trusted sources and the links are mentioned in the Appendix Slide*

# BIOSIMILARS MARKET HAS EVOLVED RAPIDLY OVER THE PAST 5 YEARS IN THE US

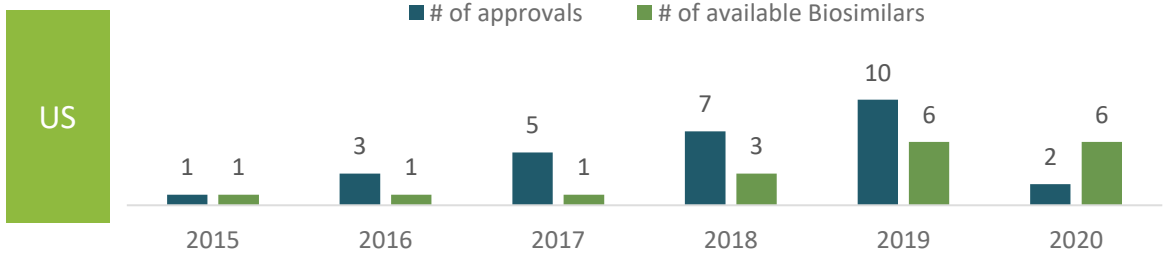
## Number of Approved vs Number of Available Biosimilars

# of approved Biosimilars - 28

# of available Biosimilars - 18

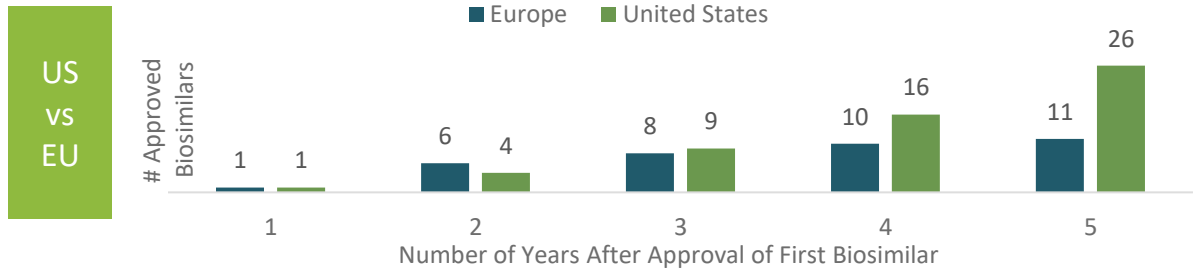
Of the biosimilars approved to date in 2020, 64% have launched and are available

Oncology TA dominates the biosimilar market with 9 biosimilars already launched



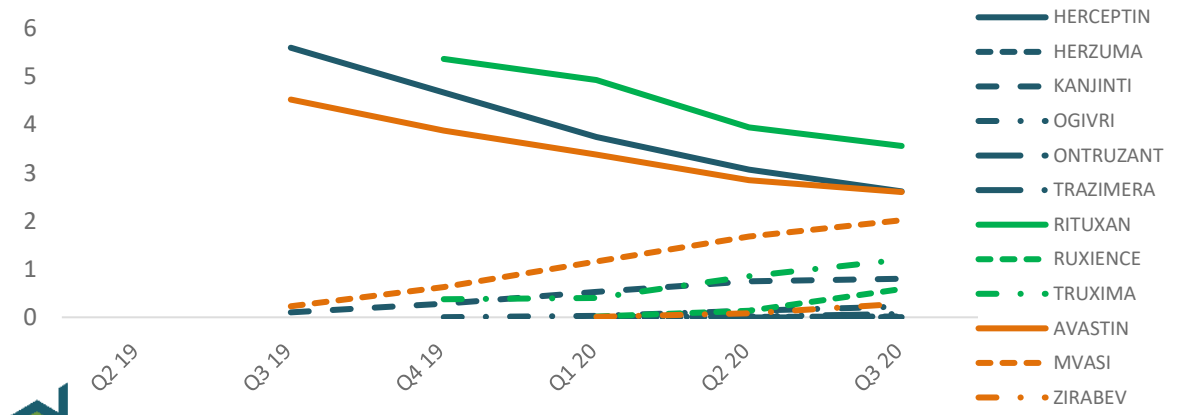

## Cumulative Number of Biosimilars Approved for Marketing in Europe vs US

US biosimilar landscape is advancing twice as fast as the EU biosimilar landscape

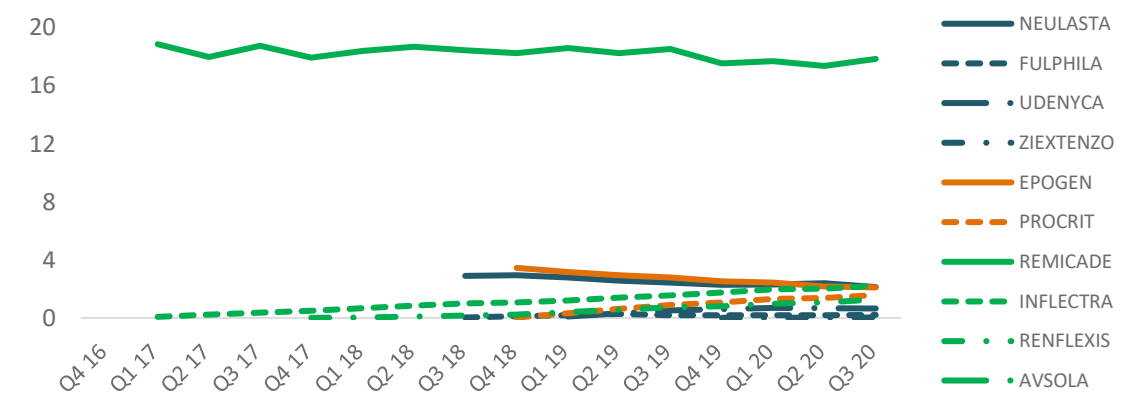



## Uptake of biosimilars in the US (in terms of Units)

### Oncology




### Supportive care / Immunology



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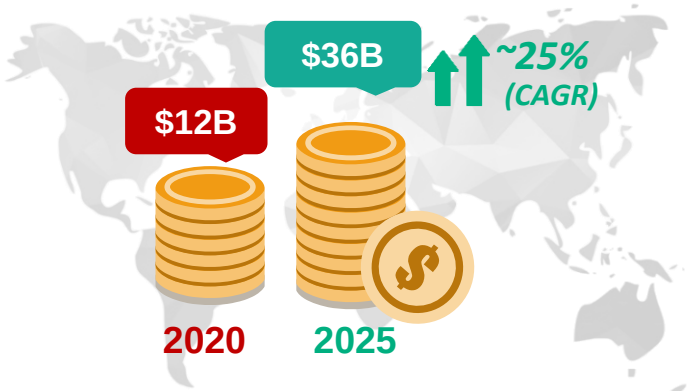
# BIOSIMILARS IS A BOOMING SPACE WITH A STRONG PIPELINE OF UPCOMING LAUNCHES OVER THE NEXT 10 YEARS

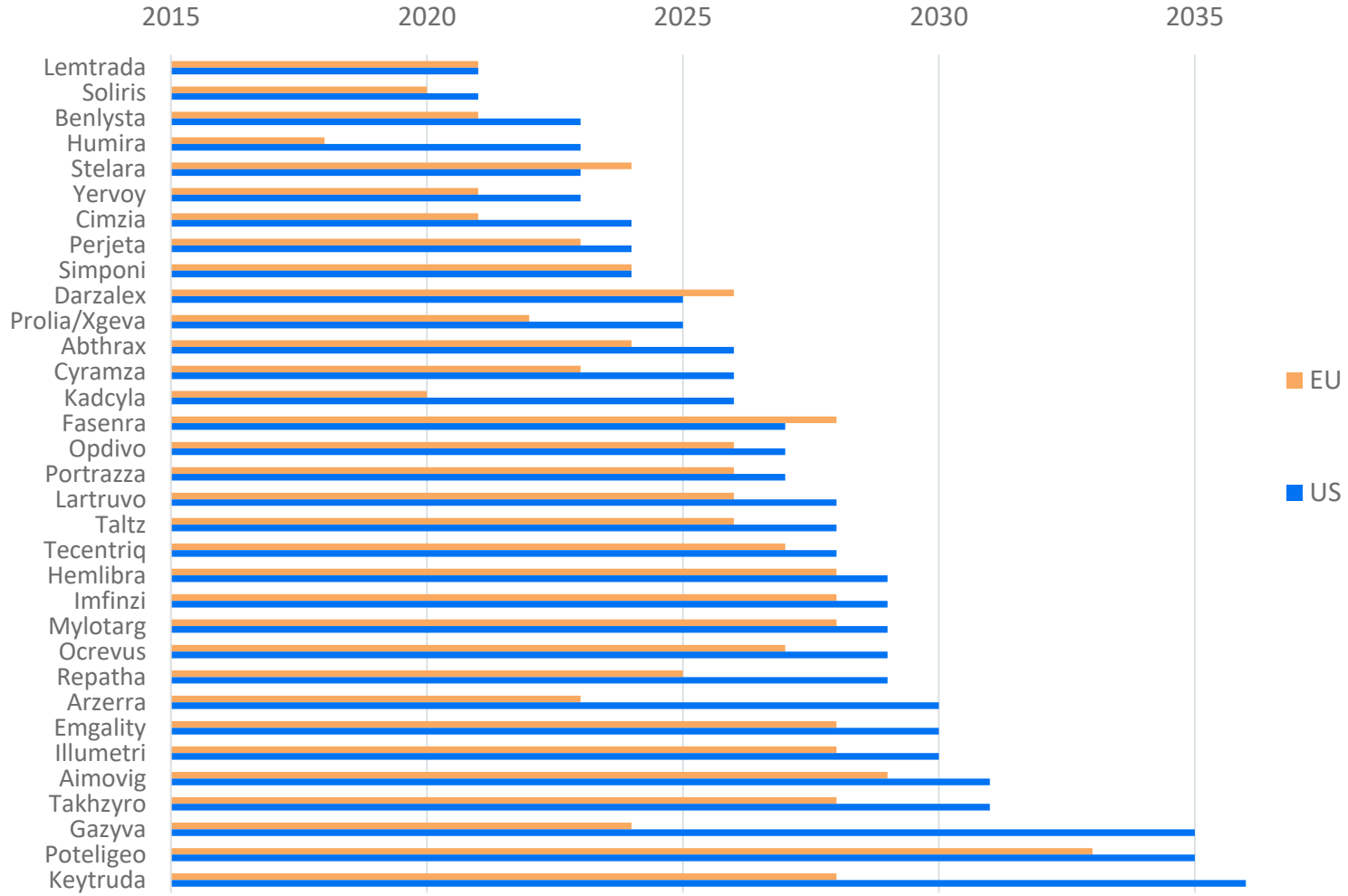
## Estimated Growth of Biosimilars




## Estimated Biologic Patent Expiries

**30+ Biologics**
**Are losing their exclusivity over the next 10-15 years**

## Key Biologics with LOE between 2021 to 2030



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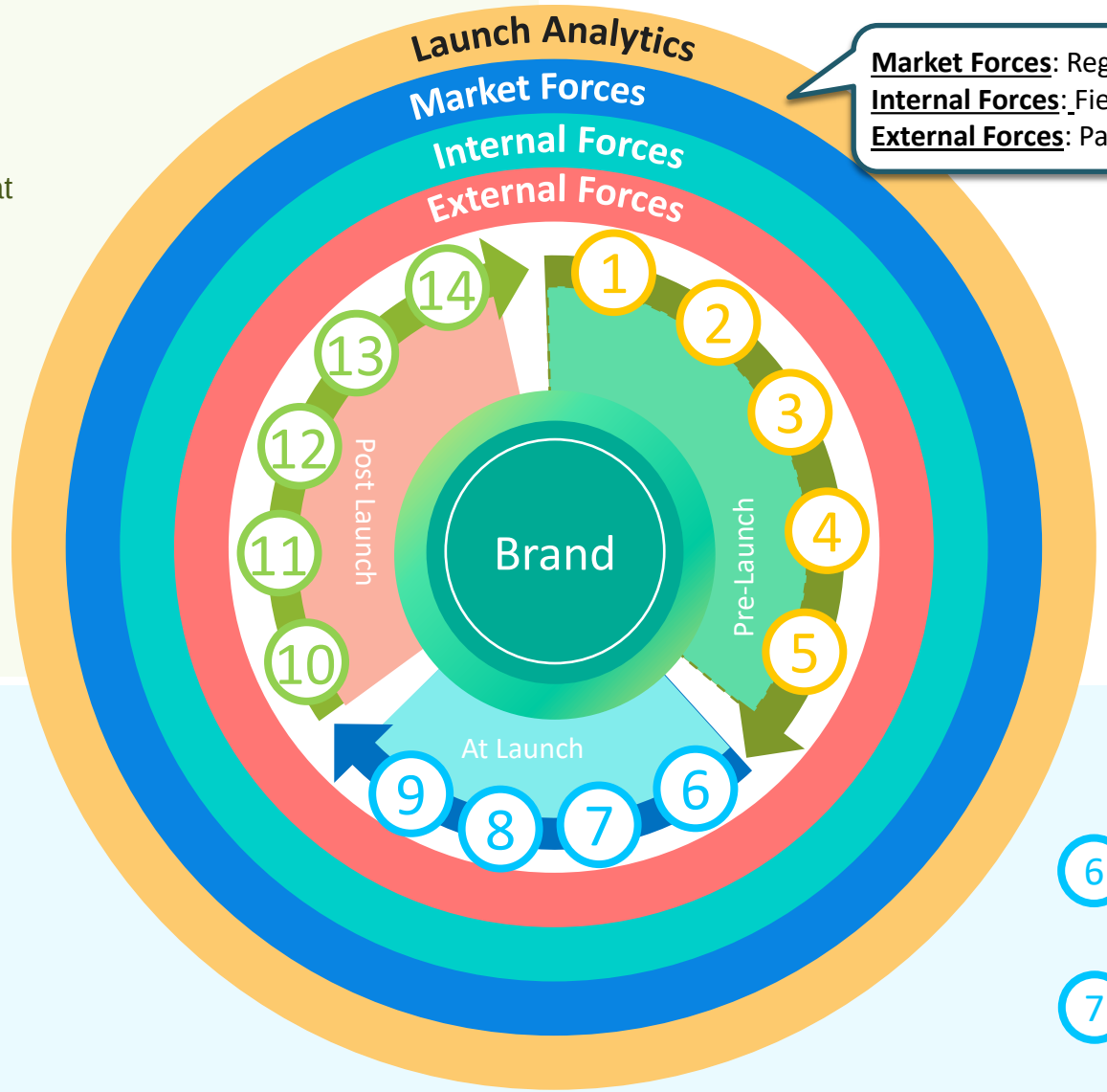
# IN THE CONVENTIONAL DRUG LAUNCH STRATEGY, EACH STAKEHOLDER JOURNEY PROVIDES A PERSPECTIVE IN TERMS OF TARGETING & MESSAGING OF THE NEW DRUG

## An Integrated Launch Analytics Framework




**Market Forces**: Regulations, Competition
**Internal Forces**: Field force/MSLs
**External Forces**: Patient, Physician, Payer

### Pre-Launch

1. Define universe of stakeholders
2. Understand Stakeholder Journeys
3. Assess brand positioning and size in the market and adjust rebates/contracts accordingly
4. Medical Team (Kol/MSL) interactions with Stakeholders to make them aware of the upcoming drug
5. IT Infrastructure setup to assist at Launch

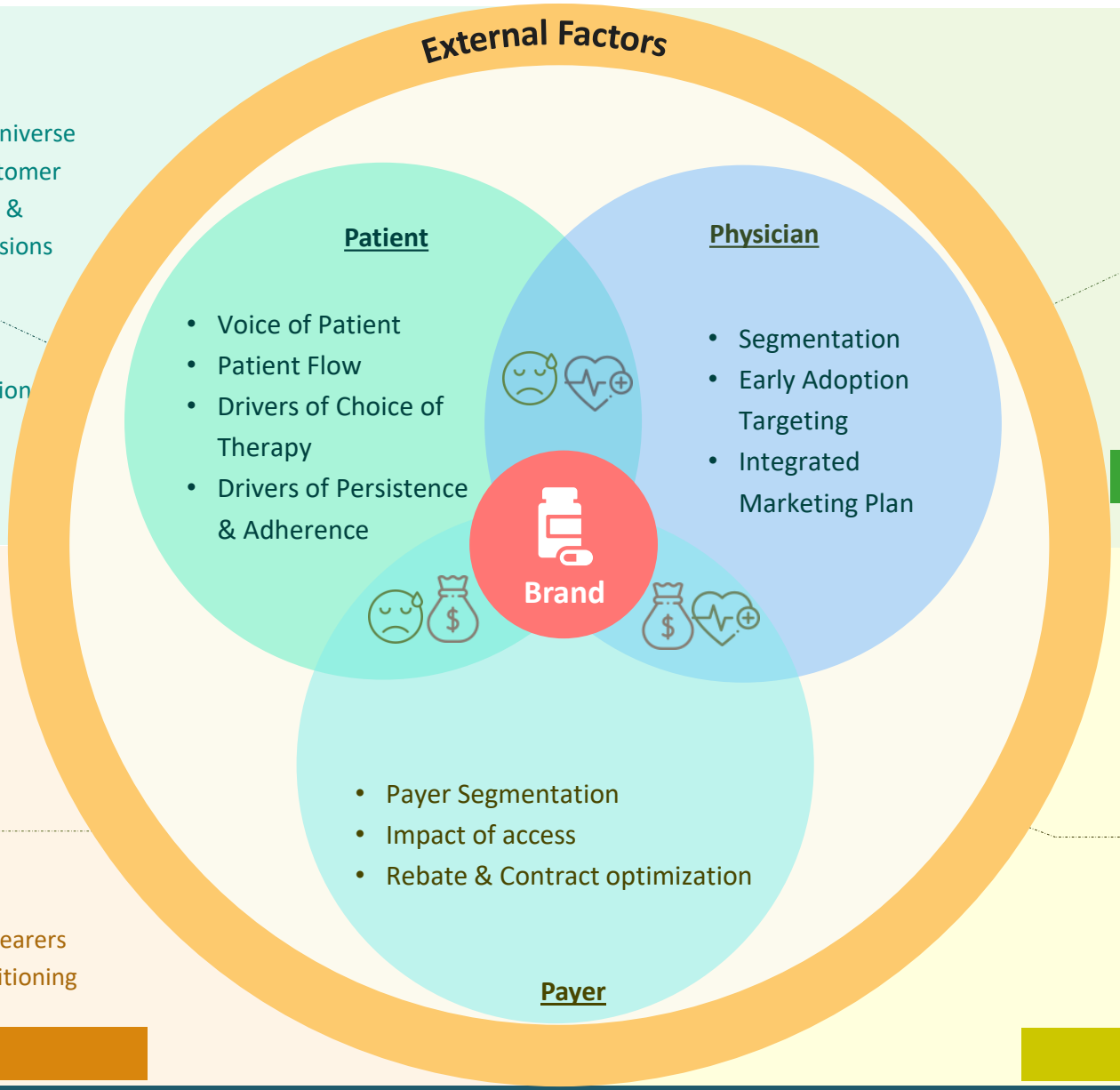
### At Launch

6. Quickly adapt targeting strategies based on outcomes
7. Onboard patients/physicians smoothly by quickly addressing drug-related issues
8. Identify market access challenges and address them
9. Developing operational agility to setup tracking and other future growth analytics

### Post - Launch

10. Track product uptake and adoption rate at different parts of the stakeholder journey
11. Monitor outcomes and HCP/Patient experiences
12. Track stakeholder satisfaction with the drug
13. Monitor patient adherence/persistency
14. Extension of line for the drug

# IN THE CONVENTIONAL DRUG LAUNCH STRATEGY, EACH STAKEHOLDER JOURNEY PROVIDES A PERSPECTIVE IN TERMS OF TARGETING & MESSAGING OF THE NEW DRUG




**Outcomes**

Develop holistic understanding of customer universe in the market of interest and drive better customer experience while minimizing revenue leakage & understanding drivers that affect patient decisions

**Insights**

Patient Cohorts of interest
Treatment Journey – Drug Switch
Population Risk & Disease progression prediction
Patient Behavior

**Claims | EMR/EHR | Social Media | RWD**

**Outcomes**

Plan & Drive an optimal omni-channel marketing & targeting strategy to reach physicians and provide them with optimal messaging

**Insights**

Physician Profiling
Outreach Program Effectiveness
Physician Targeting Planning

**SP Data | Viva Data | Sales Data | Claims**

**Outcomes**

Develop market understanding & effect of external forces on Brand and help outline and execute strategies to help tackle them during the launch phase.

**Insights**

Favorable patient profiles for brand
Physician profiling into early adaptors/ torch bearers
Payer dynamics for negotiation and brand positioning

**Claims | MMIT | Financial Data**

**Outcomes**

Understanding payer dynamics and design an optimal payer strategy to better position the drug in the market for optimal patient access, complementing marketing effort

**Insights**

Source of Business
Payer negotiation
Market Access metrics

**Claims | MMIT | Sales Data**

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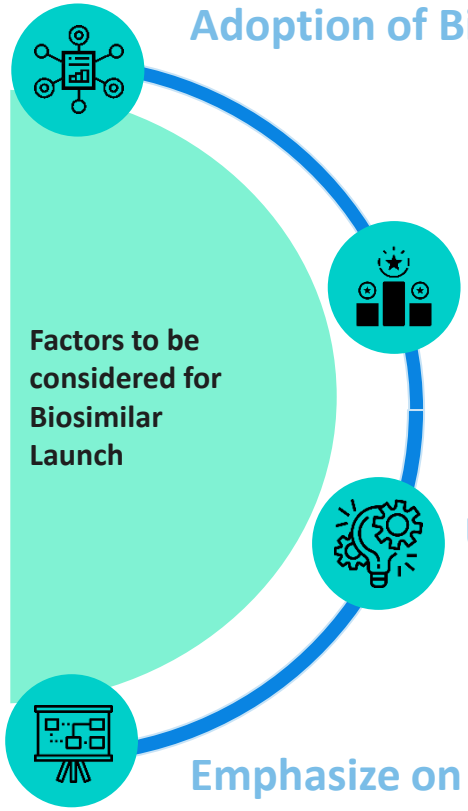
# IN ADDITION TO THE CONVENTIONAL LAUNCH STRATEGY PLANNING, IT'S VITAL TO UNDERSTAND THE NUANCES OF BIOSIMILAR MARKET TO PREPARE FOR A COMMERCIAL BIOSIMILAR LAUNCH

**Why are Biosimilars not as successful as the reference product**




## Adoption of Biosimilars by the Stakeholders

- Lack of Biosimilar coverage and the control exerted by Payers through formulary restrictions
- Broader organizational support and education/awareness hinders adoption of Biosimilars by Providers
- Unfamiliarity, parity biologic coverage and clinical reasons are the key barriers to Patient's buy-in

## Competitive environment

- In addition to the reference product, several competition posed by other biosimilars, Bio-comparables and Bio-betters make it a dynamic market
- Reduction in WAC and ASP prices of products and comparable OOP costs

## Understanding the Reference Product

- Payer and provider segments favouring the reference product
- Identifying high value opportunistic segments of patient groups
- Accessibility of reference products

## Emphasize on Differentiated Value Add

- Key differentiators: Achieving healthcare outcomes at reduced cost
- Potential other differentiators: Home infusion, Better PSPs, Reduced infusion time/frequency, Convenient form, etc.

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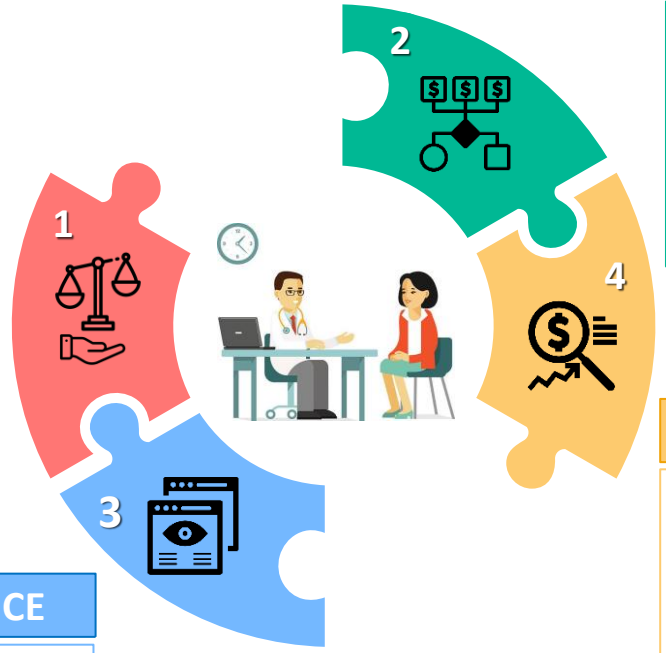
# ANALYZING THE HISTORICAL PERFERENCE OF PAYERS AND THEIR INFLUENCE & CONTROL ON THE CHOICE OF DRUG ARE THE KEY FACTORS THAT DETERMINES THE BIOSIMILAR ADOPTION IN THE MARKET

## FAVORABILITY

- Covering Biosimilars
- Biosimilars at parity/advantaged coverage
- Quicker time to favorable position
- Step restrictions imposed on Reference Product
- Biosimilar market share at-par/greater than Reference product




## COST/RISK SHARING

- Low OOP for Biosimilars vs Reference Product
- Percentage of $0 Copay is greater compared to Reference Product

## MARKET CONTROL

- Differential/Non-Differential coverage
- Change in Biosimilar shares observed after step implementations

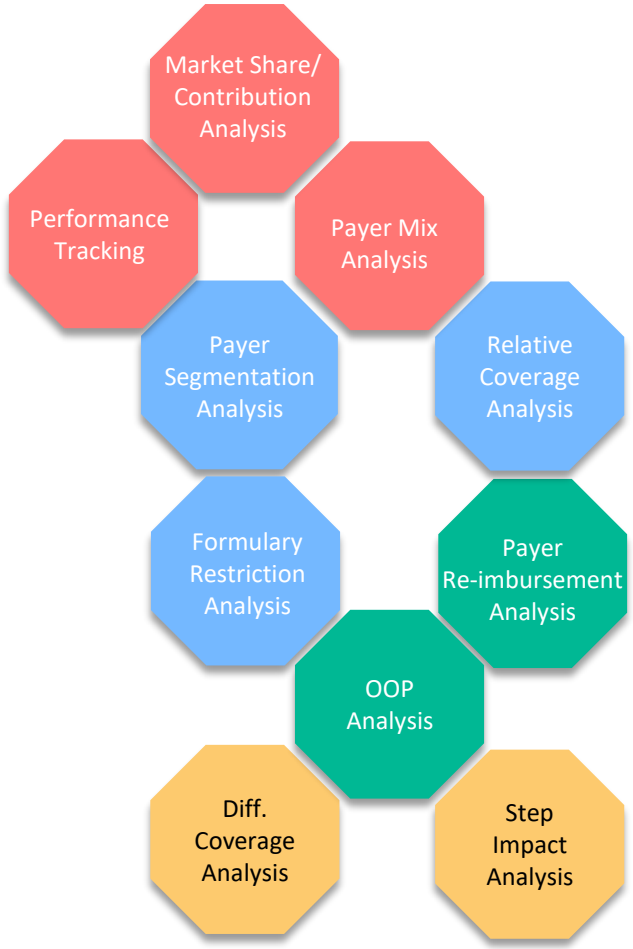
## MARKET PRESENCE

- % Contribution to market sales
- % Contribution to biosimilar sales
- % Contribution to Reference Product sales
- % contribution to overall lives

MMIT DATA

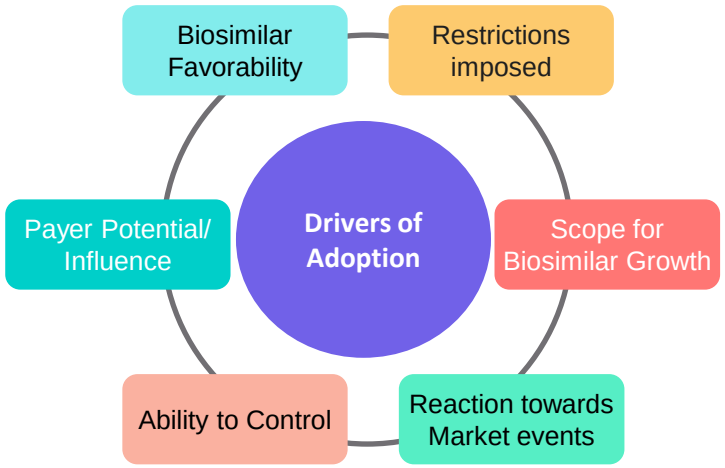
CLAIMS DATA

## Analytical Use-cases



# USE OF ADVANCED ANALYTICAL TECHNIQUES IS PRIME IN THIS ERA TO BETTER TAP INTO THE POTENTIAL OF NEW AGE DATASETS TO SEGMENT THE PAYERS FOR CUSTOMIZED & ROBUST TARGETING EXERCISE

## Key Factors



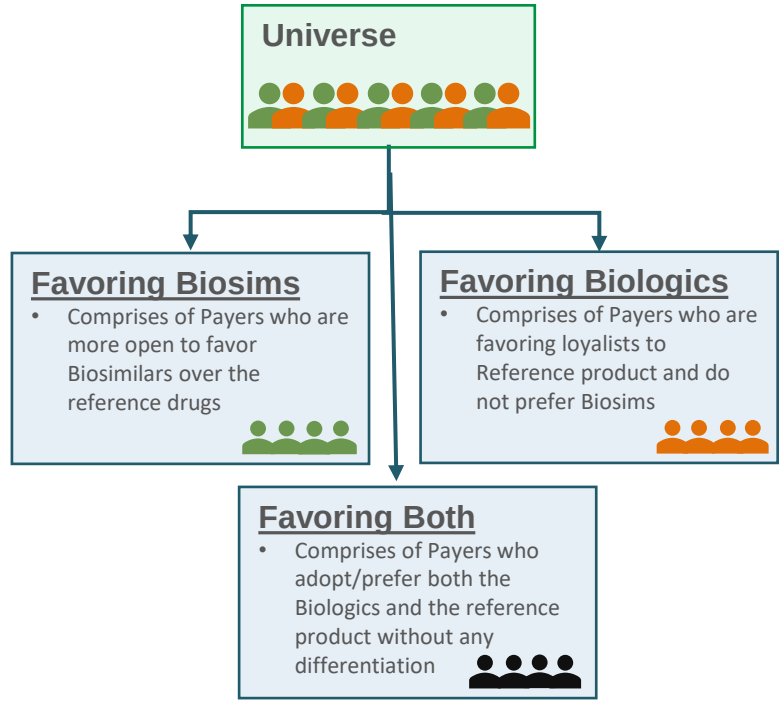

## Advanced Analytical Techniques

**Robust Classification Models** to produce highly accurate classifications of the population being studied

**Generalized Linear Models** to generate statistically significant predictions, relevant to the healthcare outcomes of interest

**Rule Based Algorithms** to apply customized business rules to garner more meaningful & relevant insights of interest

## Analytical Outputs




## Outcomes Targeted

- Understand the important factors driving biosimilar adoption among payers
- Identify the segments and have a targeted/customized marketing activities
- Effective contract strategy for quicker adoption and increased profitability

# FOCUS SHOULD BE ON TO PROACTIVELY MONITOR THE BIOSIMS ADOPTERS AND TO HAVE CONTRACT NEGOTIATIONS AND OTHER PORTFOLIO LEVEL INTERVENTIONS TO PUSH THE NON-ADOPTERS TO FAVOR BIOSIMS

Illustrative

## Experimentalists

- Payers who contributes to top 50% of market volume & top 50% of covered lives
- Payers who covers all biosimilars at advantaged coverage and have biologics at disadvantaged position
- Claims share of biosimilars is greater than 40%
- Difference in OOP of Biosimilar vs reference product is higher

**Focus on proactively monitoring & engaging to maintain the current status**

## Traditionalists

- Payers who contributes to top 50% of market volume & top 50% of covered lives
- Payers who covers all biosimilars at disadvantaged position
- Claims share of biosimilars is lesser than 30%
- Difference in OOP of Biosimilar vs reference product is lesser or negligible

**Focus on pushing biosimilars adoption through contracting strategies**

## Differentiators

- Payers who contributes to top 50% of market volume & top 50% of covered lives
- Payers who covers biosimilars with differential coverage
- Claims share of biosimilars is greater than 30%
- Difference in OOP among Biosimilars are higher

**Focus on positioning the product to eliminate the differentiation**

## Safety Players

- Payers who contributes to top 50% of market volume & top 50% of covered lives
- Payers who covers both biosimilars and biologics with similar coverage
- Claims share of biosimilars is greater than 30%
- Difference in OOP of Biosimilar vs reference product is lesser or negligible

**Focus on pushing biosimilar preference over biologics through effective contracting strategies**

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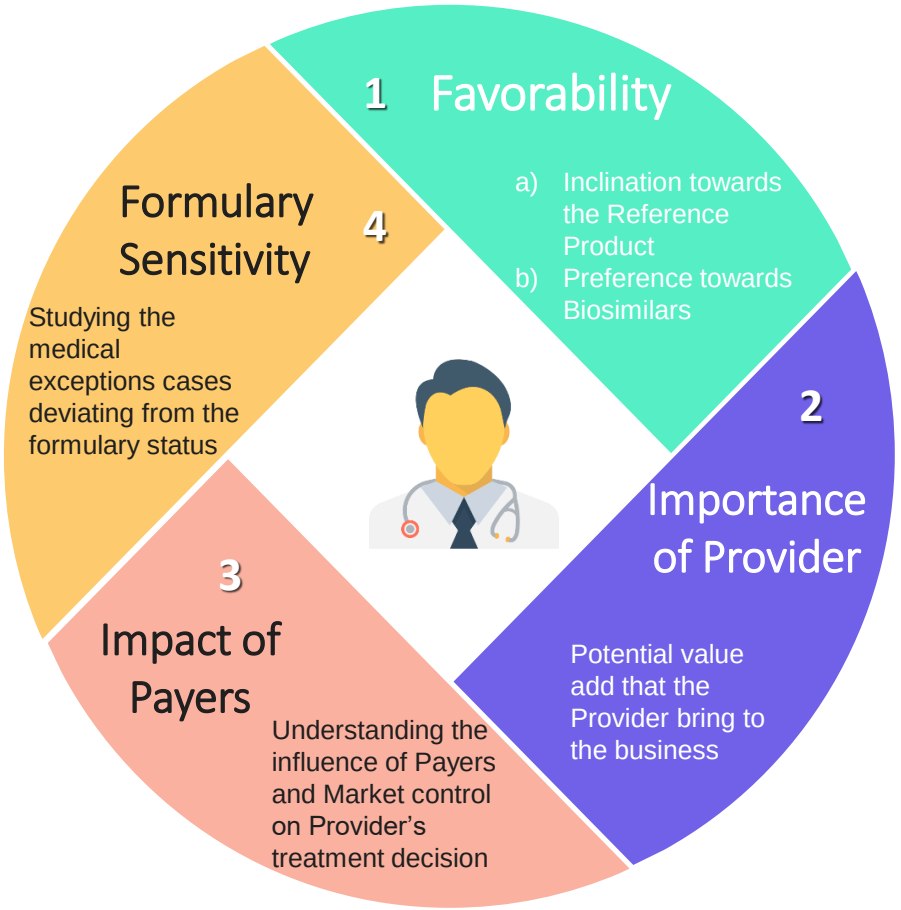
# IDENTIFYING THE RIGHT SEGMENT OF HCPs WHO WOULD BE THE POTENTIAL EARLY ADOPTERS / TORCH BEARERS IS KEY TO HAVE A HEAD START WHEN IT COMES TO BIOSIMILAR ADOPTION




**1**

- Contribution to reference product's market sales (units)
- Contribution to reference product's patient share
- Rate of uptake of biosimilars
- Usage of biosimilars

Data Sources: Xponent, DDD

**2**

- Contribution to therapeutic area level market sales
- Influencer score
  - Network score (Affiliations and Referred-in / out HCPs)
  - Clinical score (Patient count, Referred-in / out patients)
  - Thought leadership (Publications, Speaker events, CT)

Data Sources: Claims, HCOS, Xponent, DDD, PubMed, Sunshine

**3**

- Adoption / usage of Biosimilars versus control established by Payers
- % of cases of getting Prior Authorization to provide patients with the best care

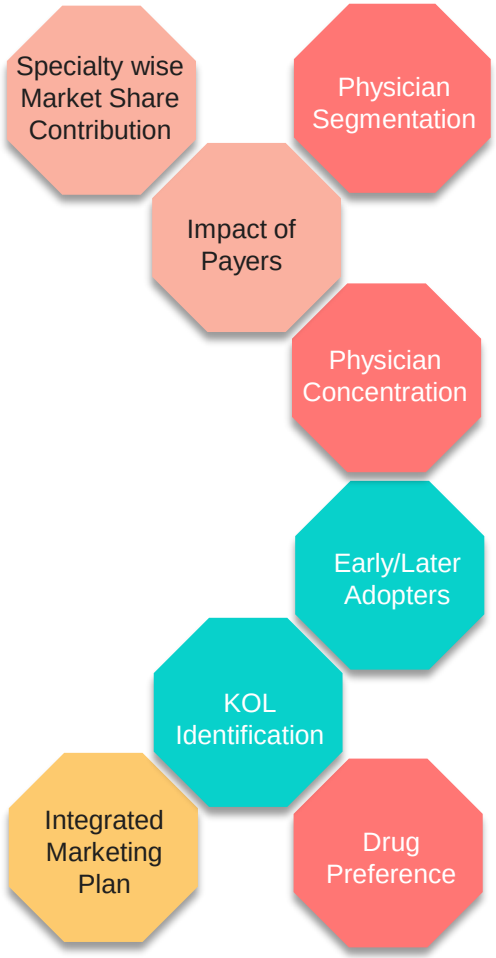
Data Sources: Claims, Xponent, DDD

**4**

- Usage of reference product despite of formulary restrictions
- Adoption / usage of Biosimilars despite of affiliation guideline

Data Sources: Claims data, Xponent, DDD

## Analytical Use-cases



# USE ADVANCED ANALYTIC TECHNIQUES LIKE SEGMENTATION TO STUDY DYNAMICS OF THE PROVIDER UNIVERSE AND DEVELOPING A CUSTOMIZED TARGETING & MESSAGING STRATEGY

ILLUSTRATIVE

## 1 CREATE A STITCHED MASTER DATASET

DATA SOURCES:
LAAD, Xponent, DDD

NORMALIZED SCORES (0,100) FOR CATALOGUE OF PROVIDERS

- Preference towards the Reference Product
- Adoption of Biosimilars
- Importance of HCP
- Impact of payer on HCP
- Adherence to Formulary Status

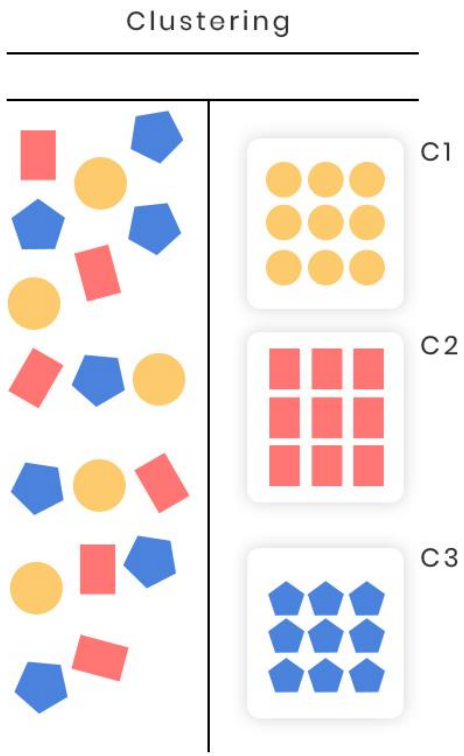
## 2 USER SELECTIONS

- MARKET BASKET
- TIME PERIOD

## 3 APPLY ENSEMBLE CLUSTERING ALGORITHMS

- k-Means
- k-Prototype
- Hierarchical Clustering
- Latent Class Clustering
- Rule based clustering

## 4 ANALYZE THE CLUSTERS & PROFILES




## 5 DESIGN STRATEGIC RECOMMENDATIONS

C1
Pioneers

C2
Late Adopters

C3
Traditionalist

# TAILOR MADE APPROACH OF TARGETING & MESSAGING IS THE NEED TO DRIVE ADOPTION OF BIOSIMILARS ACROSS THE IDENTIFIED SEGMENTS

ILLUSTRATIVE

| | Pioneers | Late Adopters | Traditionalist |
|---|---|---|---|
| **Current Behavior** | • Historic early adopters of Biosimilars<br>• High volume of Patients & Product (Biosimilars / Reference product) Usage<br>• Presents or closely involved in clinical/market events<br>• Treatment decisions are influenced by clinical/market events | • Believe in RWE and hesitate to experiment<br>• Follows a "wait and watch" strategy when it comes to new therapies<br>• Highly influenceable by KOLs/influencers while making treatment decisions | • Religiously follows the conventional treatment pathways<br>• Lower potential; low volume of Patients & Product (Biosimilars / Reference product) usage<br>• Not an active participant in conferences/speaker programs |
| Desired Behavior | **In addition to being the pioneers of early adopters of Biosimilars, act as evangelists to increase adoption of Biosimilars** | **Evaluate patients with Biosimilars early to experiment and learn** | **Switch patients with higher OOP to Biologics** |

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# REAL-WORLD DATA PROVIDE BETTER UNDERSTANDING OF BOTH THE ORGANIC AND INFLUENCED ADOPTION BEHAVIORS OF THE PATIENTS REQUIRED FOR ENHANCED AND IMPROVED TARGETING EXERCISE TO DRIVE BIOSIMILAR ADOPTION

## Key Attributes to Evaluate

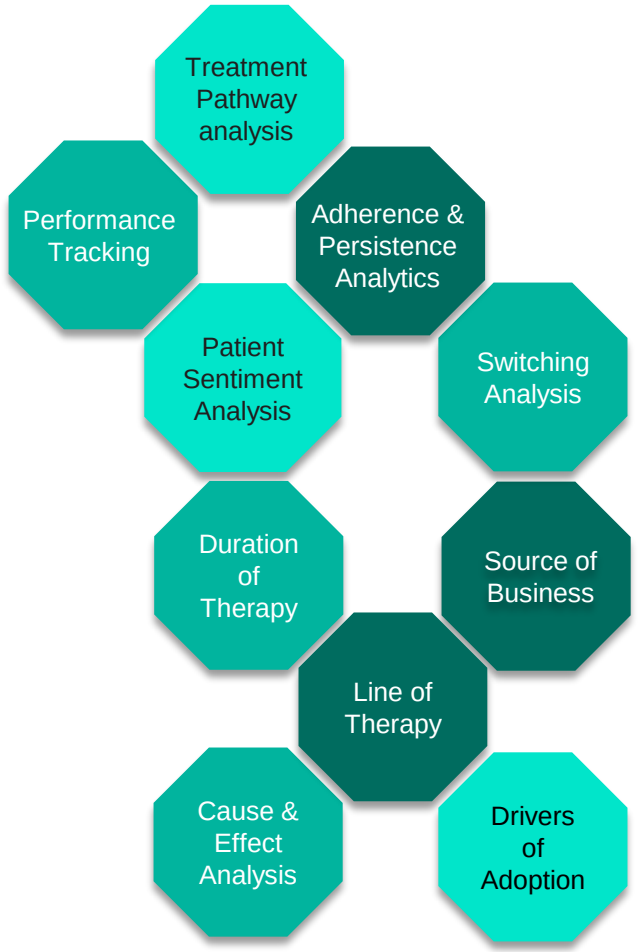
### Organic Traits

- Biosimilar preferences at different lines of treatment
- Bio-Switching Character
- Persistency on biologics vs biosimilars
- Preference of device type
- Total Amount paid by Patient
- Patient's preference in over-ruling biologics treatment
- Time taken to adopt biosimilar treatment

### Influenced Traits

- Impact of Affiliated geography
- Impact of treating Provider
- Impact of Payer coverage
- Participation in biosimilar & biologics support programs
- Impact of biosimilar/biologics sentiments on social platforms

## Analytical Use-cases




## RWD Data Sources

**Claims Data**

Contains:

- Diagnosis & treatment info
- Cost related information
- Data of insured population

**EHR Data**

- Captured at point of care
- Lab test results and other patient vitals/biomarkers not captured in claims

**Apps, Social Media**

- Captured from live health tracking
- Realtime data of patient health diagnostics
- Captures patient sentiments shared online

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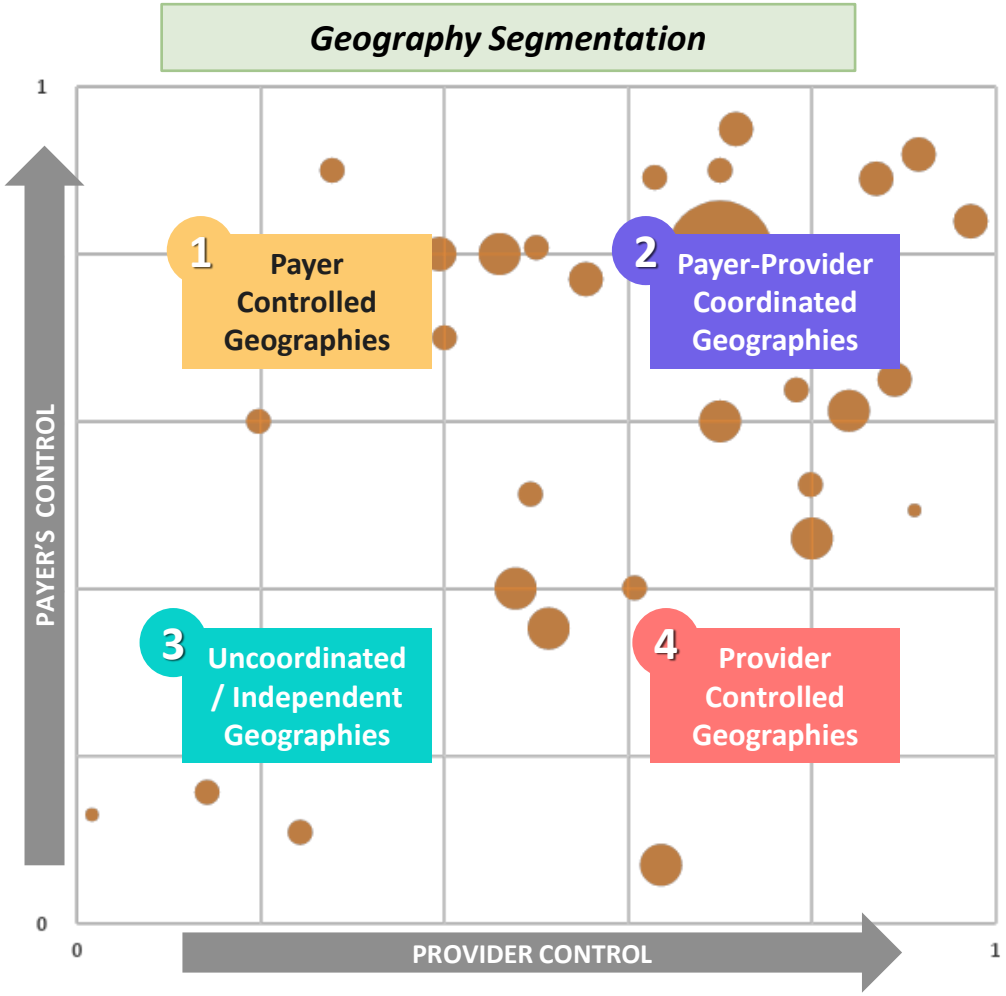
# GEOGRAPHY SEGMENTATION OF PAYER'S CONTROL ON BIOSIMILARS & REFERENCE PRODUCT VS. PHYSICIAN'S PRESCRIPTION PATTERN HELPS IN DEVELOPING TAILORED ENGAGEMENT STRATEGIES

ILLUSTRATIVE




## Payer Controlled Geographies

**Key Attributes:**

- High payer control on physician prescribing behavior of Biosimilar adoption
- High pressure on physicians to lower the overall cost and the reimbursement rates

## Payer-Provider Controlled Geographies

***Key Attributes:***

- High coordination of care between providers and payers
- High control and influence on physician prescribing behavior
- A high presence of risk-sharing institutions (ACOs), alternative payment models

## Uncoordinated / Independent Geographies

***Key Attributes:***

- Presence of independent physicians, regional payers with a little or no influence on one another
- Presence of strong field force required to win providers and payers

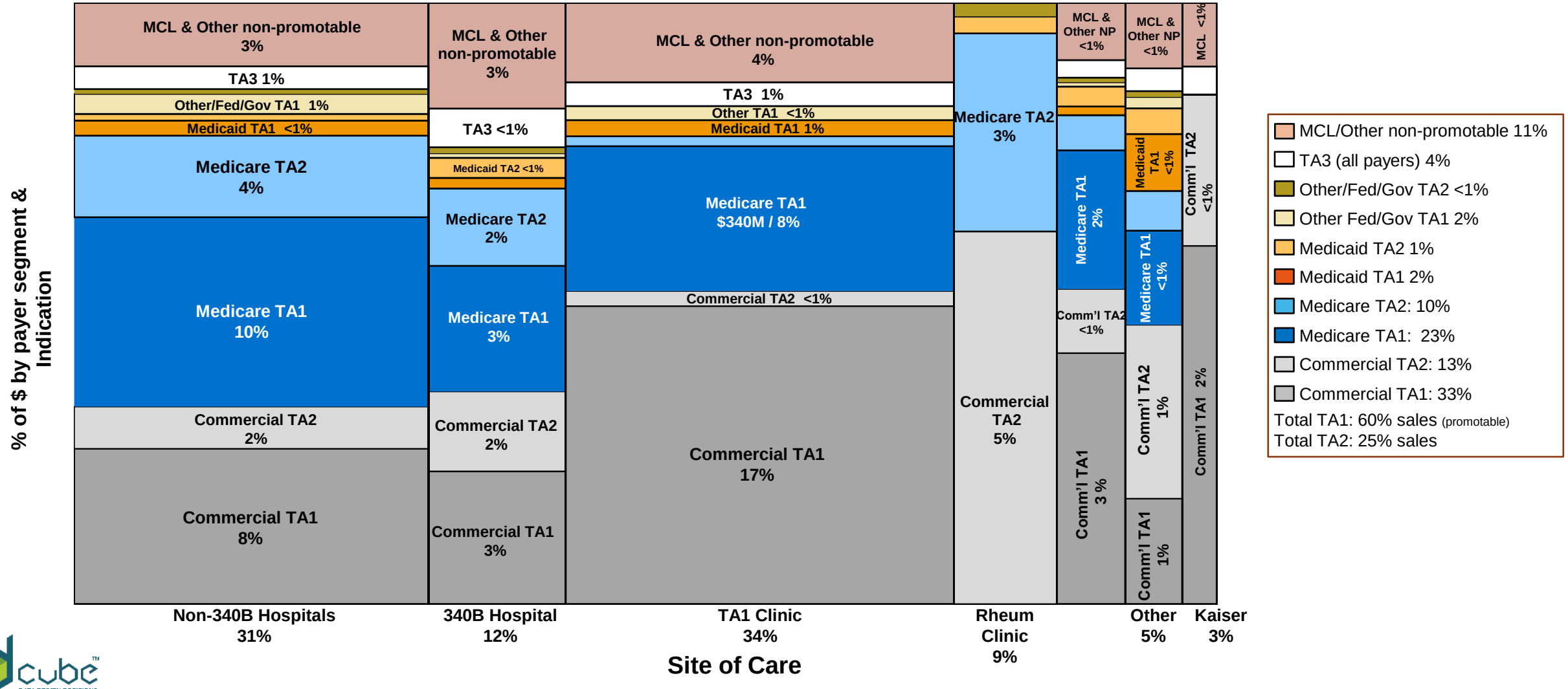
## Provider Controlled Geographies

***Key Attributes:***

- High levels of clinical care coordination
- High control on physician prescribing behavior by corporate parents
- Strong ability to negotiate the reimbursement rates from payers

# A CROSS SECTIONAL VIEW ON PAYER X INDICATION VERSES SITE OF CARE TO IDENTIFY OPPORTUNISITC BLOCKS DRIVING THE BUSINESS OF THE REFERENCE PRODUCT FOR BETTER TARGETING

ILLUSTRATIVE




- MCL/Other non-promotable 11%
- TA3 (all payers) 4%
- Other/Fed/Gov TA2 <1%
- Other Fed/Gov TA1 2%
- Medicaid TA2 1%
- Medicaid TA1 2%
- Medicare TA2: 10%
- Medicare TA1: 23%
- Commercial TA2: 13%
- Commercial TA1: 33%

Total TA1: 60% sales (promotable)
Total TA2: 25% sales

Sources: Payer Mix Data: DRG & Symphony Health, Volume Data: IMS DDD, Net Revenue: Manufacturer's Annual Financial Report, CMS ASP publication

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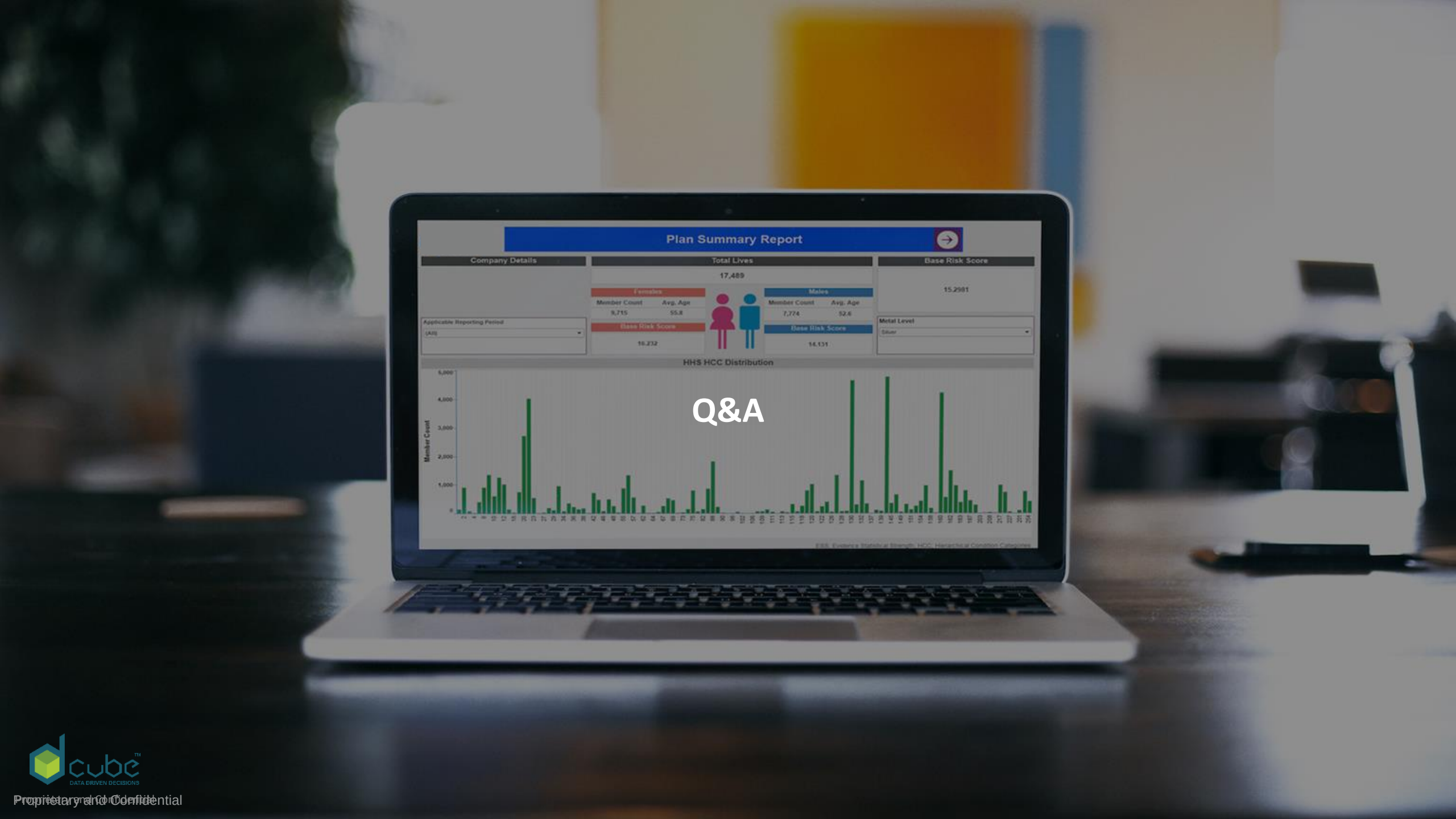
# RICH INSIGHTS FROM THIS ANALYTICAL FRAMEWORK HELP PHARMA COMPANIES IN DEVISING CONTRACTING, MARKETING AND FIELD FORCE EXECUTION STRATEGIES TO MAXIMIZE REVENUE

1. Helps in identifying the right set of payers with maximum potential to have contracts to uplift biosimilar adoption
2. Helps in identifying the payers & providers with greater ability/influence in controlling biosimilar consumption in the market for targeting purposes
3. Key input for refining, optimizing and prioritizing the physician and account target list for the field force
4. Biosimilars Reimbursement related insights can help intervene different patient profiles with copay cards and other patient support programs
5. Better assessment of patient segments for customized and improved targeting activities to promote biosimilar adoption
6. Insights regarding biosimilar preference from treatment pathway analysis can aid in data-driven targeting/educating/messaging activities to physicians and patients
7. Key input for identification and creation of KOLs list with biosimilar favorability and maximum influential network

# REFERENCE LINKS FOR SOME OF THE FACTS REPRESENTED IN THE PRESENTATION

| Slide. No. | Section | Referenced Source/Links |
|---|---|---|
| Slide 4 | How are biosimilars different from their reference product? | https://www.amgenbiosimilars.com/-/media/Themes/Amgen/amgenbiosimilars-com/Amgenbiosimilars-com/pdf/USA-CBU-80723-2020-Amgen-Biosimilar-Trends-Report.pdf |
| Slide 5 | Number of Approved vs Number of Available Biosimilars | https://www.amgenbiosimilars.com/-/media/Themes/Amgen/amgenbiosimilars-com/Amgenbiosimilars-com/pdf/USA-CBU-80723-2020-Amgen-Biosimilar-Trends-Report.pdf |
| Slide 5 | Cumulative Number of Biosimilars Approved for Marketing in Europe vs US | |
| Slide 5 | Uptake of biosimilars in the US (in terms of Units) | IQVIA MIDAS Reports |
| Slide 6 | Estimated Growth of Biosimilars | https://www.marketsandmarkets.com/Market-Reports/biosimilars-40.html |
| Slide 6 | Key Biologics with LOE between 2021-2030 | http://gabi-journal.net/patent-expiry-dates-for-biologicals-2018-update.html |
| Slide 6 | Estimated Biologic Patent Expiries | |



# READY TO TEST DRIVE THE NEW PARADIGM?

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