Session 108, Outcome Based Risk Sharing Arrangements – From Theory to Practice

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Outcomes Based Risk Sharing Agreements (OBRSAs)

From Theory to Practice

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Introductions

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Merck & Co. Inc.

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Actuarial Manager, Pharmacy Advisory Services
Optum

Agenda

Who?	What?	How Long?
Karl	Context	10 minutes
Jim	OBRSAs details, varying stakeholder perspectives and incentives, barriers, and case example	30 minutes
Whitney	Overview of the actuarial methods	20 minutes
Audience & Panel	Q&A	15 minutes

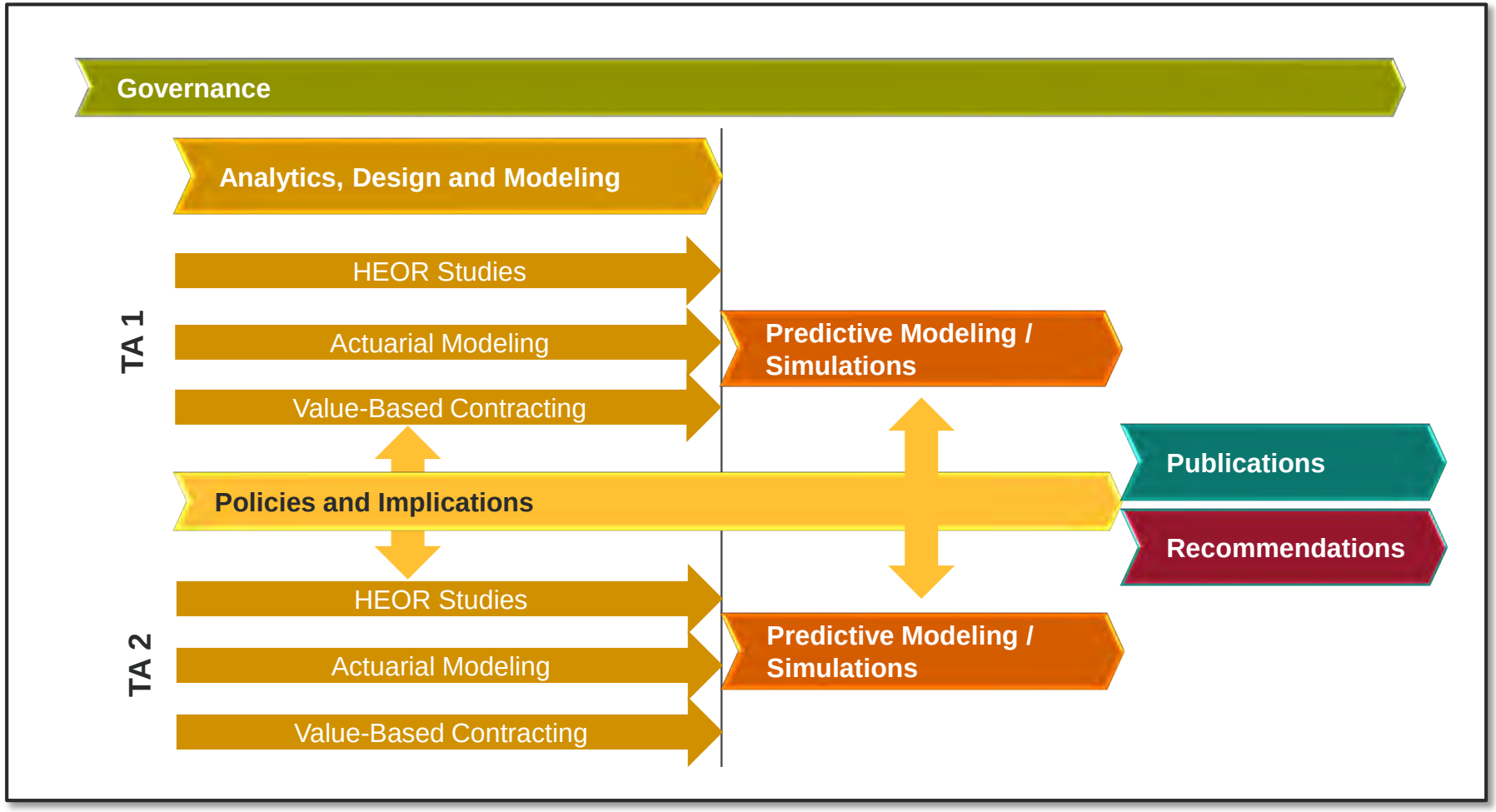
Context

- Pharmaceutical innovations vs. growing drug budgets
- Improved patient outcomes vs. challenges predicting and managing drug costs
- Actuaries paying closer attention to financial risk associated with pharmaceuticals
- Overall health system's move away from a fee-for-service environment
- Increasing focus on value-based payments
- Interest in also linking reimbursement for pharmaceuticals to treatment outcomes and benefit design
- Value-Based Contracts (VBCs) may also be referred to as:
  - Risk-sharing agreements
  - Performance-based risk-sharing arrangements
  - Managed entry agreements
  - Patient access schemes
  - Coverage with evidence development
  - Outcomes-based risk sharing agreements (OBRSAs)

Context (Continued)

- Over a 2-year period, Merck and Optum collaboratively conducted an initiative meant to inform the methodology behind, and design of, OBRSAs
- The overarching purpose was to inform the development and execution of OBRSAs in the 3-5 year timeframe
- More specific goals were to:
  - Identify data, methods, measures and contractual structures that most efficiently and effectively quantify the value for various stakeholders
  - Better understand the types of variables, populations, and clinical characteristics that are most predictive of clinical and financial outcomes
  - Explore new models and modeling methods
  - Define stakeholders with whom such agreements may be most promising
- Identify prevailing and evolving policy issues, and recommend how such issues must be considered in the development and prospective testing of outcome-based risk contracts
- Structured as a “learning laboratory,” the initiative focused on immediate learning rather than immediate success or failure in designing and testing innovative OBRSA models

Overview Of Work Streams



2019 Health Meeting

JIM LI, FSA, MAAA, MERCK & CO., INC.

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Pharmaceutical Executives at Senate Hearing

Bourla and other executives repeatedly said they favored "value-based" reimbursement, under which drugmakers would get paid based on the number of strokes their medicines prevented or the number of cancer patients in full remission, "rather than the number of pills we sell," Bourla said.

By **Christopher Rowland**
February 26

The Washington Post

Quick Survey

- How many of you ever participated in any kinds of performance-based arrangements between health plans (Payer) and health care providers (hospital systems, clinic centers, physician groups etc.)?

- How many of you ever participated in any kinds of outcome-based risk sharing arrangements (OBRSAs) between health plans (Payer) and pharmaceutical companies (Pharma)?

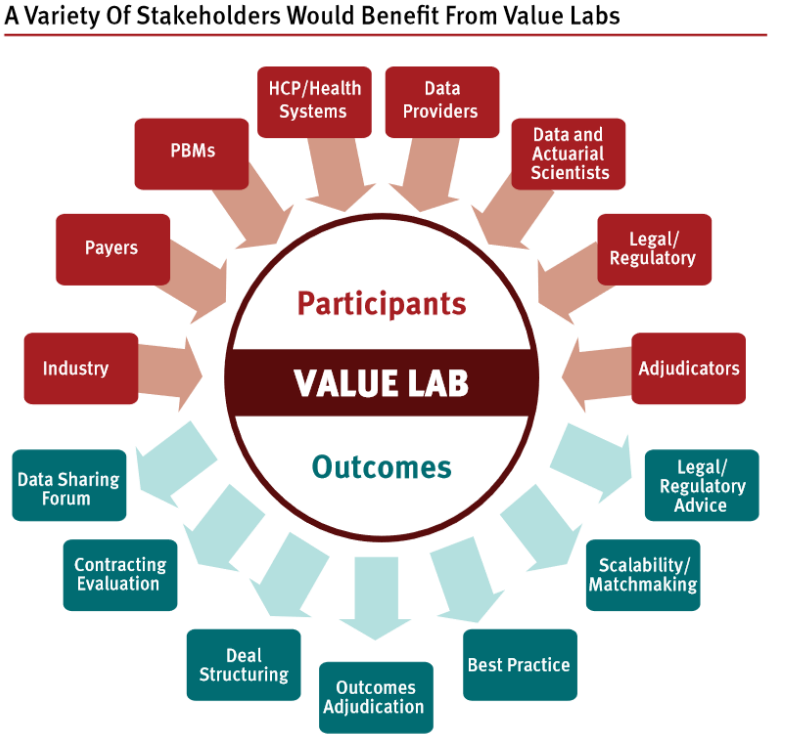
What Is Outcome Based Risk Sharing Arrangements (OBRSAs)

Key Concepts

- Multiple stakeholders
- Patient-centered outcomes
- Risk sharing

Participants

- Primary
  - Pharmaceutical Manufacturers (Pharma)
  - Health Plans (Payer)
- Others
  - Healthcare Systems (e.g. hospitals, clinics, physician groups etc.)
  - Data Providers
  - Adjudicator (a third party vendor)



Reference: In Vivo, July/August 2017, "The Value Lab", by S. Garfield et al.

What Is an OBRSA

Definition -

Any contractual agreement between a pharmaceutical manufacturer and a payer in which the reimbursement of a therapeutic is tied to the clinical outcomes it provides in the real-world

Compared with Traditional P4P* Models -

- Key difference – Value versus Volume
- Value Concept difference – Clinic/Economic Effectiveness versus Quality/Cost
- Disease difference – Specific Disease versus Comprehensive Coverage
- Population difference – Limited Patients versus Insured Population

*P4P – pay for performance

Recent Value-Based Pharma Contracts (around 20 for recent 10 years in the U.S.)

Year	Therapeutic Area/Disease	Drug	Pharma Company	Payer	Notes
2019	Cardiovascular	Brilinta	AstraZeneca	UPMC for Life (MA)	Two sided risk
2018	Substance Abuse	Vivitrol	Alkermes	UPMC Health Plan	Positive clinic outcomes linked reimbursement
2018	Diabetes	Jardiance	Boehringer Ingelheim	UPMC Health Plan	Population total costs of care lined reimbursement
2018	Diabetes	Praluent	Sanofi/Regeneron	Expresss Scripts	lowered cost and shared rebates with consumers
2018	Cancer	Kymriah	Novartis	Various	No pay if not meeting milestones
…					
2017	Cholesterol	Repatha	Amgen	Harvard Pilgrim	Money back guarantee if experiencing myocardial infarction/stroke while on drug
2017	Osteoporosis	Forteo	Eli Lilly	Harvard Pilgrim	Adherence linked reimbursement
2016	Diabetes	Trulicity	Eli Lilly	Harvard Pilgrim	Two sided risk, money back guarantee
…					
2009	Diabetes	Januvia and Janumet	Merck	Cigna/Aetna	blood sugar linked formulary placement and OOP expenses
Reference: Darwin Research Group, January 2019 Update on VBC Pharmaceuticals					

OBRSAs – Different Incentives/Interests

Payers

- Mitigate outcome uncertainty risk
- Control healthcare cost growth by avoiding spending for not-as-expected outcome
- Alternative access to closed formulary position
- Seek RWE to facilitate medical management
- Good public relationship

Pharmaceutical Manufacturers

- Demonstrate therapeutic values and facilitate innovation
- Expand/secure therapeutic access
- Increase differentiation competition advantages
- Innovate pricing/reimbursement options
- Generate RWE for new-to-market products
- Good public relationship

* RWE – real world evidence

OBRSAs - Barriers to Implement

Legal/Regulatory Barriers

- Health Care Economic Information Communication (HCEI)
  - FDAMA 114 (1997)
  - 21st Century Cures Act. (2016)
  - FDA HCEI Guidelines (2018)
- HIPAA
  - Protect PII/PHI
  - Limits/conditions on use and disclosure
- Anti-kickback Statute (prohibit the following)
  - Reimburse payers/providers due to defective devices
  - Support payers/providers with EHR software/analytic tools
  - Offer payers/providers discount due to undesired outcomes
- Medicaid Best Price
  - Discounts/rebates associated with OBRSAs will result in the changes of the calculation of rebate over all national transactions

Operational Barriers

- Administrative Burden
  - No norm, no industry standards, no widely accepted best practice models
  - Lack capabilities
  - On-going efforts (data collect/health status monitor/adjudicate etc.)
- Agreed-upon Outcomes
  - Patient inclusion criteria
  - What outcomes meaningful
  - How to measure/settle
- Data Infrastructure/accessibility
  - Existing infrastructure not sufficient
  - Access other data sources (EHR/EMRs)
  - Share data among stakeholders
- Unaligned Incentives
  - Value culture
  - Trust relationship

* EHR - electronic health record; HCEI – health care economic information

OBRSAs - Opportunities

- Develop trust relationship by guaranteeing clinical outcomes, or “money-back”
- Identify mutual beneficial goals, including
  - ❑ Consider different payers’ budget priorities/value definitions when exploring contracts (e.g.NCQA quality measures);
  - ❑ Develop Clinic trial / real world data based disease predictive capabilities to enhance payers’ medical management
  - ❑ Include in the contract the provision of sharing adjudication fee between pharma and payer
- Establish a long term two-way dialogue for mutual benefits with payers
- Explore appropriate ways to address other OBRSA implementation barriers

OBRSAs – Application Limitations/Considerations

- Not all drugs applicable for the OBRSAs, but focus on high cost specialty products with significant clinical and financial impacts
- Some therapeutic areas lack of clear/measurable outcomes are not good candidates
- Therapeutic areas with competition in the market are on the higher position of priority list
- The appropriate timing for OBRSA arrangements vary depending on specific drugs and/or pharma commercial strategies (e.g. mostly pre-commercial stage)
- The incentives/needs for different payers vary significantly (e.g. different size insurance companies, HMOs, employer sponsors, PBMs etc.)
- Innovative pricing/reimbursement options are subject to regulation constraints (e.g. combo-therapy pricing, extra discounts/rebates, etc.)
- Patient variations in real world add outcome uncertainty
- Patient eligibility isolation should be contingent on drug adherence

OBRSAs – Move to Practice

Focus is to address practical issues

- Identify payer/pharma incentives and capabilities
- Align incentive gaps between payer and pharma
- Address data sharing/informatics capability issues
- Identify meaningful/measurable outcomes and agreed-upon by pharma/payer
- Design financial arrangements based on the clinical outcomes
- Monitor patient treatment data and measure treatment outcomes
- Settle the arrangements

Case Study – An OBRSA Between Pharma and Payer

General Introduction

Partners	
	Genentech (Pharma) vesus Priority Health (Payer)
Medicine	
	Avastin
Disease	
	Non Small Cell Lung Cancer
Purposes	
	Build Strategic Relationship between Pharma and Payer, ensuring right patients on the right medication

Reference: 4/3/2017 Health Affairs Blog, by John Fox, Marc Watrous

Case Study – An OBRSA Between Pharma and Payer

Key Considerations

a) Leadership Buy-in

- allowing exploration and trial

b) Which Medicine

b1) clearly defined outcomes

b2) outcomes can be observed in a relatively short timeframe (<1 year)

b3) measurable (reliable and objective)

c) Definition and Metrics

- Progression Free Survival (PFS) as surrogate endpoints for Overall Survival (OS)

d) Data Issues

d1) Payer responsible for tracking health status/collecting and reporting patient-level longitudinal data

d2) but payer systems cannot evaluate clinical and outcomes data (need EHR)

d3) balance specificity and simplicity to make operation practical

e) Government Pricing Reporting

e1) Medicaid Best Price

e2) 340B ceiling pricies

e3) Medicare ASP calculation (for Part B coverage)

Case Study – An OBRSA Between Pharma and Payer

Design and Structure

a) Inclusion Criteria

- diagnosis codes
- no chemotherapy within last 6 months
- no diagnosis of lung cancer within 60 days

b) Metric/Outcome

- Outcome: Progression Free Survival (PFS)
- Metric threshold: 6 months

c) Outcome Measurement

- measure PFS at individual patient level
- calculate and verify PFS from claims, imaging, and EHR data
- if no imaging study, payer reviews oncology office/infusion center/inpatient EHR
- if no electronic records, payer obtain records from treating oncologist

Case Study – An OBRSA Between Pharma and Payer

Design and Structure

d) Financial design: tie rebates to PFS

- if PFS >= 6 months, payer rebate = 0
- if claims indicate patients were on Avastin for >6 months
  deemed threshold met, and payer rebate = 0
- if interval between 1st and last dose < 6 months, agree to reason:
  if switch due to patient/provider preference, no rebate
  if switch proved due to toxicity or progression, rebate is paid
- rebate is paid directly proportional to the magnitude of the difference between actual and expected PFS

Case Study – An Illustration Example

Exhibit - Example Contract Calculation (not reflective of actual financial terms)

Median PFS for 1st line disease as threshold	**12 months**
For patient A, the following is observed:	
PFS	**10 months**
Goal missed by/unrealized benefit	**2 months**
Realized benefit	**10/12 = 83%**
Unrealized benefit	**2/12 = 17%**
Risk Sharing agreement if threshold is not met	**50%**
Duration of treatment	**10 months**
Drug cost per month	**$10,000**

Case Study – An Illustration Example

Exhibit - Example Contract Calculation (cont'd)

Risk-sharing calculation

Total treatment cost	**10 x $10,000 = $100,000**
Unrealized benefit	**17%**
Risk sharing portion	**50%**
Refund amount	**$100,000 x 17% x 50% = $8,333 rebate**

In this example, the pharma would rebate the payer $8,333, which results in a net yield of ($100k-$8.3k)/$100k, or around 92%.

Questions?

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2019 Health Meeting

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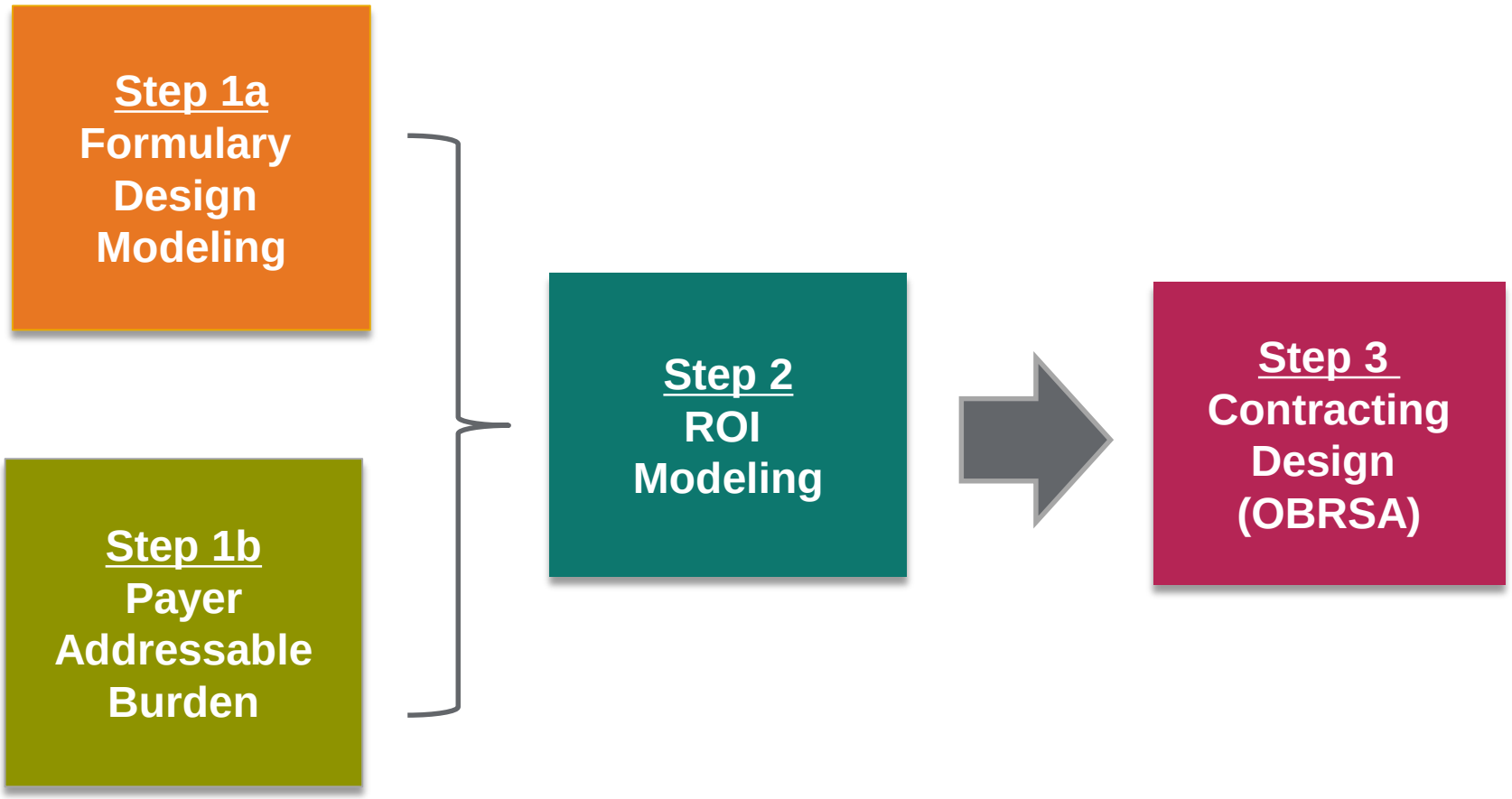
Actuarial Modeling Overview



OBRSA = Outcomes Based Risk Share Agreement

Summary of Actuarial Analyses & Models

Formulary Design Model	• Identify net cost of new drug and other drugs on the market for disease state • Determine potential utilization
Payer Addressable Burden Analysis	• Identify areas of cost savings opportunity (population subsets, high spend areas, etc.) • Estimate costs that may be saved due to using new drug
Return on Investment Model	• Determine current costs to a plan for identified members • Estimate potential costs/savings to a plan assuming additional spend and medical savings due to new drug • Determine return potential

Formulary Design Model

Goal of the Analysis	
	• Estimate potential treatment population size • Determine net cost impact of new drug and other drugs entering the market

Example Summary of Findings

Utilization Estimate Calculations

1. Currently treated disease population
2. Increase in utilization due to new drugs on market
3. Impacts of utilization mgmt programs

	Net Cost per 30d Rx (2021)*
Drug 1	$100
Drug 2	$120
Drug 3	$400

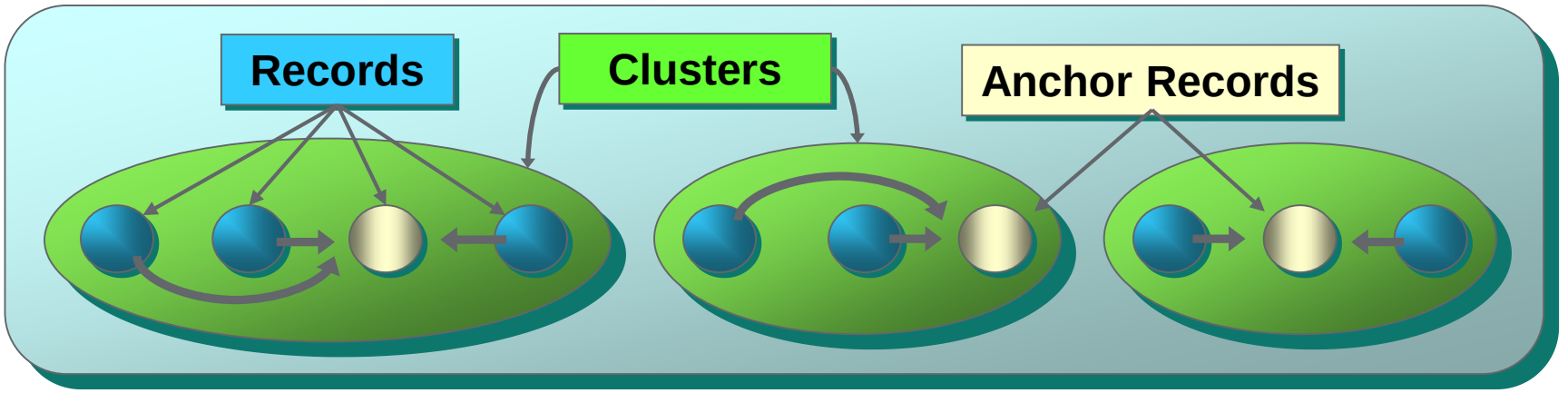
*Numbers here are for illustrative purposes only

Critical Insights	
	• Uncertainty/certainty of impacted population • New drug utilization compared to other drugs currently used for treatment (length of use, cost)

Episode Treatment Groups

Symmetry® Episode Treatment Groups® (ETGs) software was used to help with grouping claims for applicable disease state.

- ETGs provide a condition classification methodology that combines related services into medically relevant and distinct units describing complete EOCs and associated costs



- Each cluster has only one anchor record
- Each claim line can be assigned to one, and only one, episode of care

Payer Addressable Burden

Goal of the Analysis	
	• Determine average cost of a less and more severe population (“low” & “high” cost groups) • Review how costs differ by population sub-groups

Example Summary of Findings

Average Annual Cost to Plan*

	Commercial	Medicare
Low Cost Group	$X	$Y
High Cost Group	$X * 1.2	$Y * 1.5

*Med + Rx

Critical Insights	
	• Potential for savings if members do not escalate to more severe states of disease • Costs associated with main disease, associated comorbidities, ER visits, hospitalizations, etc.

Return on Investment (ROI) Model

Goal of the Analysis	• Estimate plan's total investment in new drug • Estimate potential savings due to delaying or avoiding increased severity of disease state

Summary of Findings

Net Savings/(Cost) to Plan per Utilizer per Year

	Commercial	Medicare
1-Yr ROI	-$1000	$4000
2-Yr ROI	+$3000	$5000
5-Yr ROI	+$5000	$6000

*Numbers here are for illustrative purposes only

Critical Insights	• Savings potential may or may not be sufficient to off-set cost of new drug • Identify most sensitive assumptions, breakeven estimates of drug costs, and cost areas with highest potential for savings

Actuarial versus HEOR Approaches

Common Foundations	Divergent Approaches and Applications	
	Actuaries	Health Economics & Outcomes Research
Calculus-Based Statistical Theory	Law of Large Numbers (minimize statistical variation)	Characteristic-Matched Studies (minimize confounding factors)
Measuring Results	Estimate Confounding Factors	Eliminate Confounding Factors
Health Economic Impact	Financial Outcomes	Clinical & Economic Outcomes
Dealing with Uncertainty	Book of Business Focus	Disease Focus
Model-Building Experts	Identify Correlations	Identify Causations
	Short/Intermediate-Term Horizons	Intermediate/Long-Term Horizons
	Up-front iterative	Back-end iterative