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Digging Deeper: Uncovering Expanded Patient Insights Through Linked Data

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Panel introductions

- **Heather von Allmen**
  CorEvitas, LLC
  Sr. Director, Licensing and Partnerships

- **Scott Robinson, MA, MPH**
  Inovalon Insights
  VP, HEOR

- **Scott Henderson, MS**
  CorEvitas, LLC
  Sr. Director, Linked Data Analysis

Poll: Now let us get to know you

What sector of the industry do you represent?

(select all that apply)

A. Pharmaceutical/Life Science Company

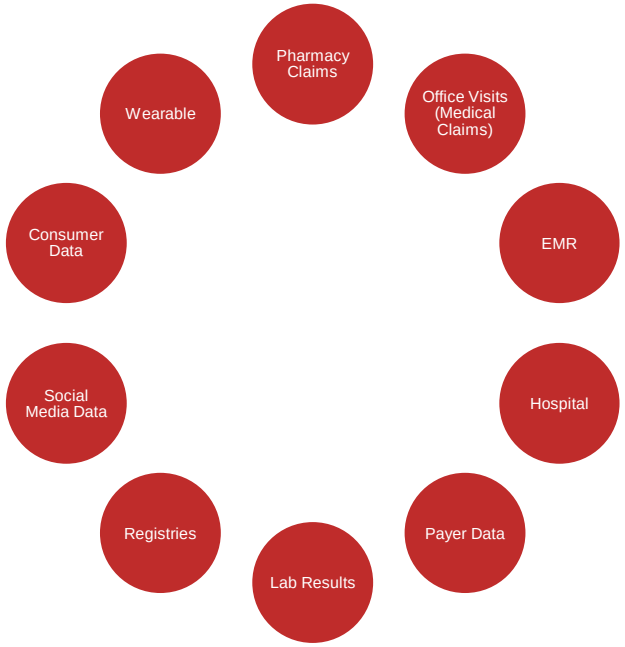
B. Real-World Data Vendor

C. Consulting Company

D. Academia/Student

Considerations When Designing RWE Studies Using Linked Datasets

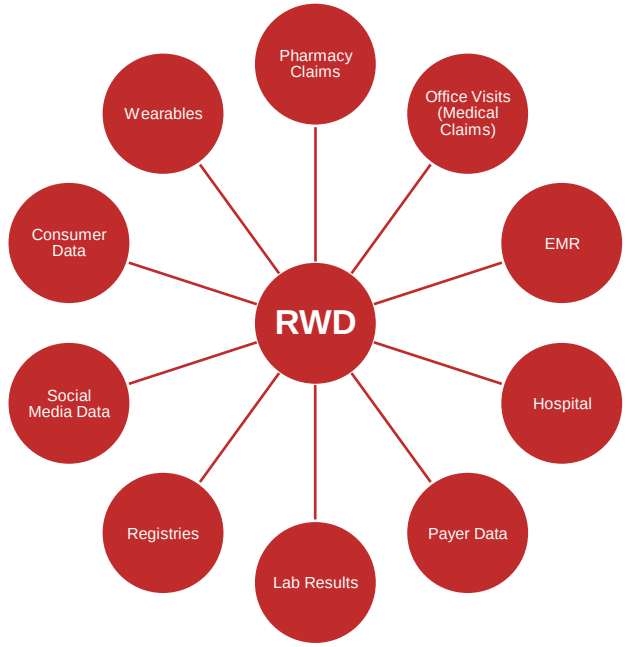
Barriers to working with a variety of real-world data sources are being eliminated with common encryption methodologies and secure token exchange



Encryption methods are company-specific: Linking to multiple datasets requires installation of multiple encryption engines

Demand increases for more robust RWD in Life Sciences

Companies provide tokenization services and secure token exchange across companies to address, addressing RWD demand



Historically, data was utilized in silos or within a single company

In recent years, companies have been created to enable secure linkages across data sources

This has made it easier for companies to select data combinations that are best fit for purpose

Poll: What types of real-world data have you used in studies?

Select all that apply

A. Open claims sources (e.g., pharmacy, office, hospital)

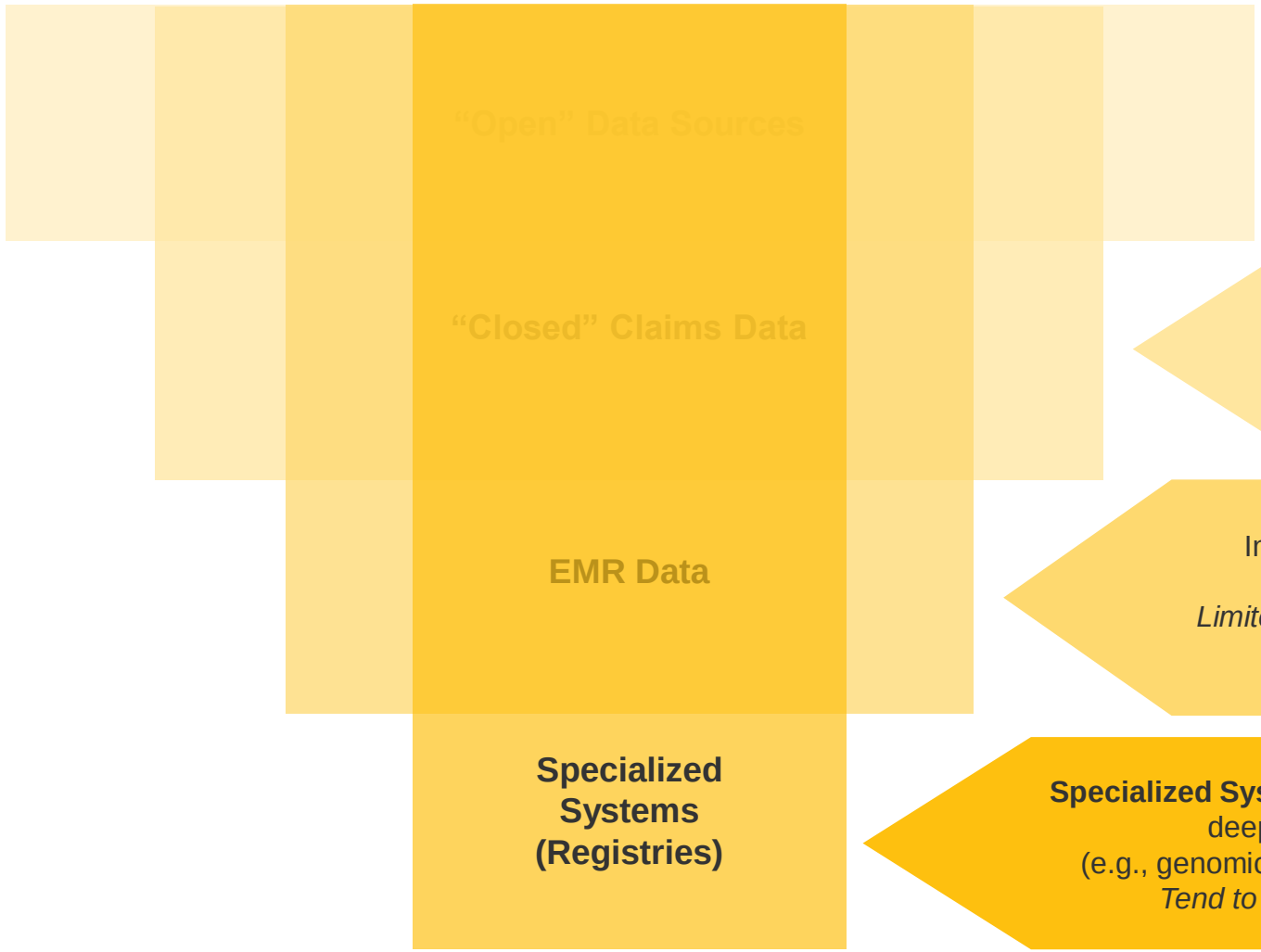
B. Closed claims sources (e.g., private payor, Medicare)

C. EMR data

D. Laboratory results or genomic data

E. Patient registries or patient reported outcomes (PROs)

When evaluating the best fit for purpose, the characteristics of each data source and its strengths/weaknesses must be considered



Large Open Data Sources:
Capture large populations but with a specific focus (e.g., prescription or office claims; consumer data)
Good for answering broad questions for forecasting or tracking business over time

Closed Claims Data:
More robust than large open sources, as it covers all activity for an insured population
Limited to time period when a patient is insured and to fields captured for reimbursement

EMR Data:
Includes clinical information from patient management systems
Limited to select physicians and patient records from only those physicians
Free text data requires data mining

Specialized Systems: Captures very specific or deep data on individuals (e.g., genomic databases, registries, PROs)
Tend to cover small populations

Through linking, these detailed sources can be used to supplement the broader RWD sources

Analyses conducted on the overlapped population allow a deeper view of patient behaviors

The first step in study design is to align on study objectives and critical data needs for outcomes evaluation

Objectives of Analysis

- Examples:
  - In patients diagnosed with a specific condition, compare HCRU by treatment
  - Compare healthcare resource utilization by treatment and adjust for clinical metrics (e.g., disease severity)

Outcomes and Data Needs

- Epidemiology
- Patient journey
- Disease activity and progression
- Healthcare resource utilization and cost of care
- Treatment effectiveness
- Cost effectiveness
- Survival
- Validation of published studies or algorithms

Potential Data Sources

- Administrative Claims
- Clinical Registry or Trial Data
- Consumer
- EMR
- Hospital Charge Master
- Laboratory/Diagnostic Results

Additional limitations and consideration for linked studies will include available sample size, generalizability, and privacy considerations

Sample size and representativeness: single source vs. linked data

Trade-off of additional data elements vs. restrictions in sample size

Does approach allow for appropriate statistical comparisons?

Addressing duplicate or conflicting information between sources

Maintaining de-identification of the combined data

Examples of an Administrative Claims Dataset and a Clinical Registry for use in Linked RWE Studies

1. Closed Claims

Primary Sourced Closed Claims Data Provides Longitudinal view of Patient Transaction Data

Multi-Payer Inputs

Payer Data Accessed

- Quality Insights
- Risk Insights
- Star Ranking Measures
- CMS 100% Medicare FFS Data

Value of Data Processing

Longitudinally linked, normalized, validated claims data, delivering a

Longitudinal Claims Data Asset

Value of Closed Claims Data Assets

Tokenized Claims for Data Linking

Advanced Analytics

Monthly Updates from Payer Sources

Patient, provider, and claims-level data are used in real-world evidence studies

Commonly Used Claims Data Elements in RWE Studies

- Unique patient ID
- Birth year, gender, state, Zip3
- Insurance type (primary)
- ACA indicators

Patient / Subscriber

- NPI
- Address
- Provider taxonomy/ specialty
- Facility/institution type

Provider

- Claim type (prof./institution)
- Place of service
- Service dates
- Standardized costs

Claim

- Diagnosis codes
- Procedure codes (CPT, HCPCS, ICD)
- DRG
- NDC (on Rx)

Diagnosis / Procedure

2. Registries

Registries are explicitly designed to provide RWE for safety and regulatory uses, within specific conditions

Data Collection

- Data are collected **prospectively, using *structured* data fields** in registry questionnaires completed by physicians and patients
  - Data are **"fit for purpose"** as defined by 21st Century Cures
  - Data are *not* extracted from free text EMR notes
- **Comprehensive, granular safety data** are collected, including information about serious adverse events (SAEs)
  - Data that may not be captured or asked about in a routine clinical encounter with a specialist
- Detailed source documents are collected to support reporting of SAEs and AEs of special interest (targeted AEs), enabling case validation by drug safety specialists

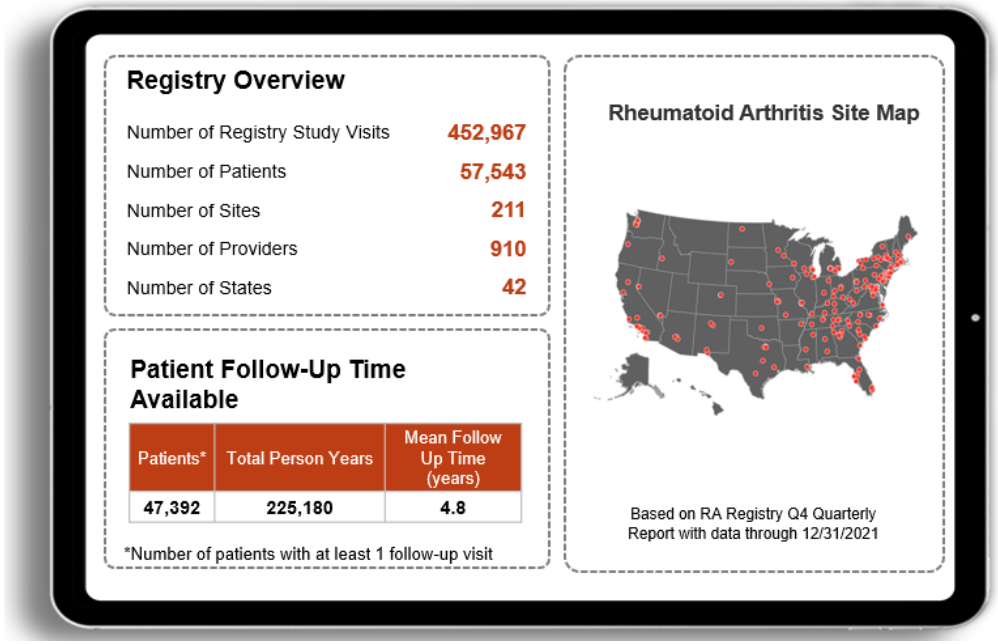
Major Regulatory Use Cases

- **Post-Authorization Safety Study (PASS)** to meet FDA and EMA requirements as part of new drug approval post marketing requirements (PMR)
- **Secondary indication approval** by leveraging safety data in primary indication as part of regulatory submission
- **US regulatory approval to extend label** for approval as monotherapy, extending the current approval as combination therapy

Registry data are typically narrow in scope but deep in clinical data captured, collecting gold-standard clinical, safety, and PRO measures

Typical Attributes of Registries:

- Data are captured across the US
- Multiple investigator sites are utilized
- Long-term patient enrollment is common
- Deep clinical measures are captured



Example: Registry for Rheumatoid Arthritis

Demographics and Lifestyle	Age Gender Height Weight	Education Work status	Body Mass Index Smoking Status Alcohol use
Disease Characteristics	RA Duration 28 Joint Count, ACR Functional Class Physician Global Assessment		
Disease Activity and Treatment Response	CDAI DAS28 SDAI ACR20/50/70		
Patient Reported Outcomes	Patient Global Assessment of Pain, Fatigue, Arthritis HAQ EQ-5D-3L AM Stiffness		
Lab Measures	RF Positive CCP Positive		
Treatments	Treatment initiation (dose and frequency) Prior medication (biologics, biosimilars, non-biologic DMARDs)		

Poll: What applications do you see benefiting most from linked data?

Please rank (1=most beneficial)

A. Adherence

B. Cost Effectiveness

C. Healthcare Resource Utilization and Cost

D. Patient Journey

E. Treatment Effectiveness

EXAMPLE USE-CASE:

Deeper Insights into Healthcare Resource Utilization using Linked Claims and Registry Data

Linking claims data with patient registries: Healthcare Resource Utilization (HCRU)

Current Situation

- Claims data traditionally are used as a reliable source for measuring HCRU

Unmet Need

- Not all patients consume healthcare resources at the same rate
- Manufacturers could better understand how different segments of patients utilize healthcare, which could impact outcomes

Solution

- By linking measures of disease activity and patient reported outcomes from registry data to administrative claims data, insights can be gained into the HCRU of meaningful patient segments

Administrative Claims Data:

- The nature of claims data ensures that all activities associated with a patient's care are captured
- Limited to information recorded for the purposes of reimbursement

Patient Registry Data:

- Purpose-built to capture clinical measures directly from physicians and patients, including disease duration and disease activity based on validated composite outcome measures
- Limited by data collection sites, so may not reflect the full spectrum of healthcare encounters

Linked Data:

- In claims data, analyses of patient behavior and outcomes are limited to the population as a whole or segmented by proxy clinical measures
- Linkage of registry data to claims data can enhance the insights derived from claims data alone

Poll: What is the average annual medical cost of patients with rheumatoid arthritis who have moderate/high disease activity, relative to patients in remission?

A. More than 100% higher

B. 67% higher

C. 33% higher

D. No difference

Linking claims data with patient registry data: Healthcare Resource Utilization

Background:

- Treat-to-target guidelines recommend achieving remission or low disease activity in rheumatoid arthritis (RA). However, the reduction in adverse events and costs associated with lower disease activity is unclear

Objective:

- Evaluate clinical and economic outcomes associated with lower disease activity states
- Serves as an example of a linkage between an outpatient disease registry and administrative claims to address a scientific question for which both types of data would be required

Methods:

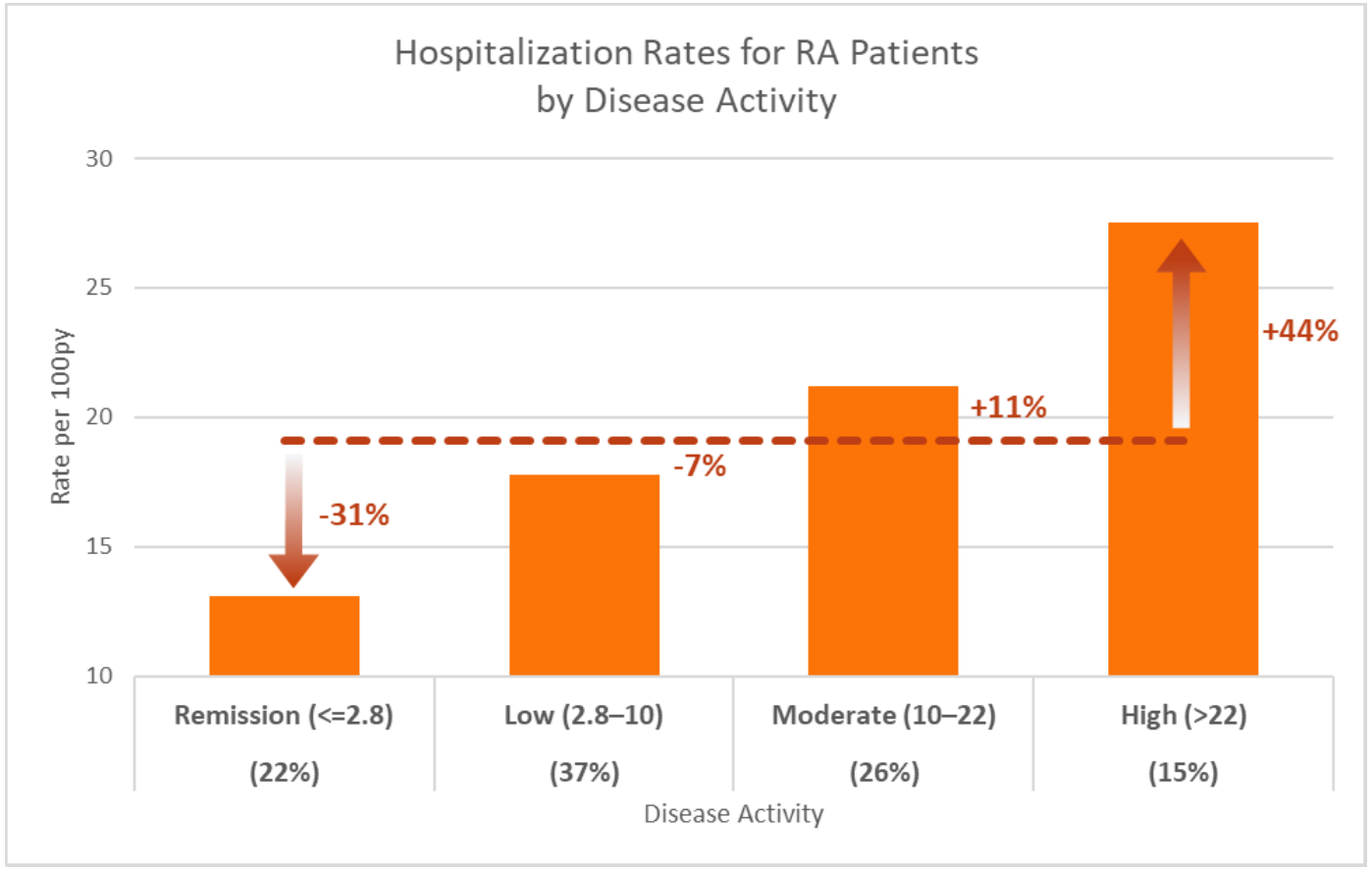
- RA patients selected from the CorEvitas Rheumatoid Arthritis patient registry, linked to Medicare administrative claims data.
- Disease activity was measured using the Clinical Disease Activity Index (CDAI) from the registry data
- Outcomes were derived from the administrative claims data, including all-cause hospitalization, a composite of hospitalization or emergency department (ED) visits, mortality, and medical costs

Types of questions that can be addressed by the unique combination of administrative claims data and clinical registry data

- *Are clinical and economic outcomes associated with disease status?*
- *Does a lower disease activity state impact other outcomes including healthcare services?*
- *Is lower disease activity associated with fewer ED visits, a lower likelihood of all-cause hospitalization, a lower risk for all-cause mortality, and lower healthcare costs?*
- *What are the merits of achieving low disease activity targets?*
- *What is the economic impact of more aggressive RA treatments to achieve more intensive disease activity targets?*

Curtis JR, Chen L, Greenberg JD, Harrold L, Kilgore ML, Kremer JM, Solomon DH, Yun H. The clinical status and economic savings associated with remission among patients with rheumatoid arthritis: leveraging linked registry and claims data for synergistic insights. Pharmacoepidemiol Drug Saf. 2017 Mar;26(3):310-319.

Linking claims data with patient registry data: Healthcare Resource Utilization – Hospitalization Rates



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If the analysis were conducted with claims data alone, the average hospitalization rate would have been estimated to be 19.1 (per 100 person-years).

Segmenting by clinical measures shows a correlation between disease activity and hospitalization rates.

Without the ability to segment by disease severity, the estimated hospitalization rate would have:

- Over-estimated the rate by 31% for patients in remission (22% of patients)
- Under-estimated the rate by 44% for patients with high disease activity (15% of patients)

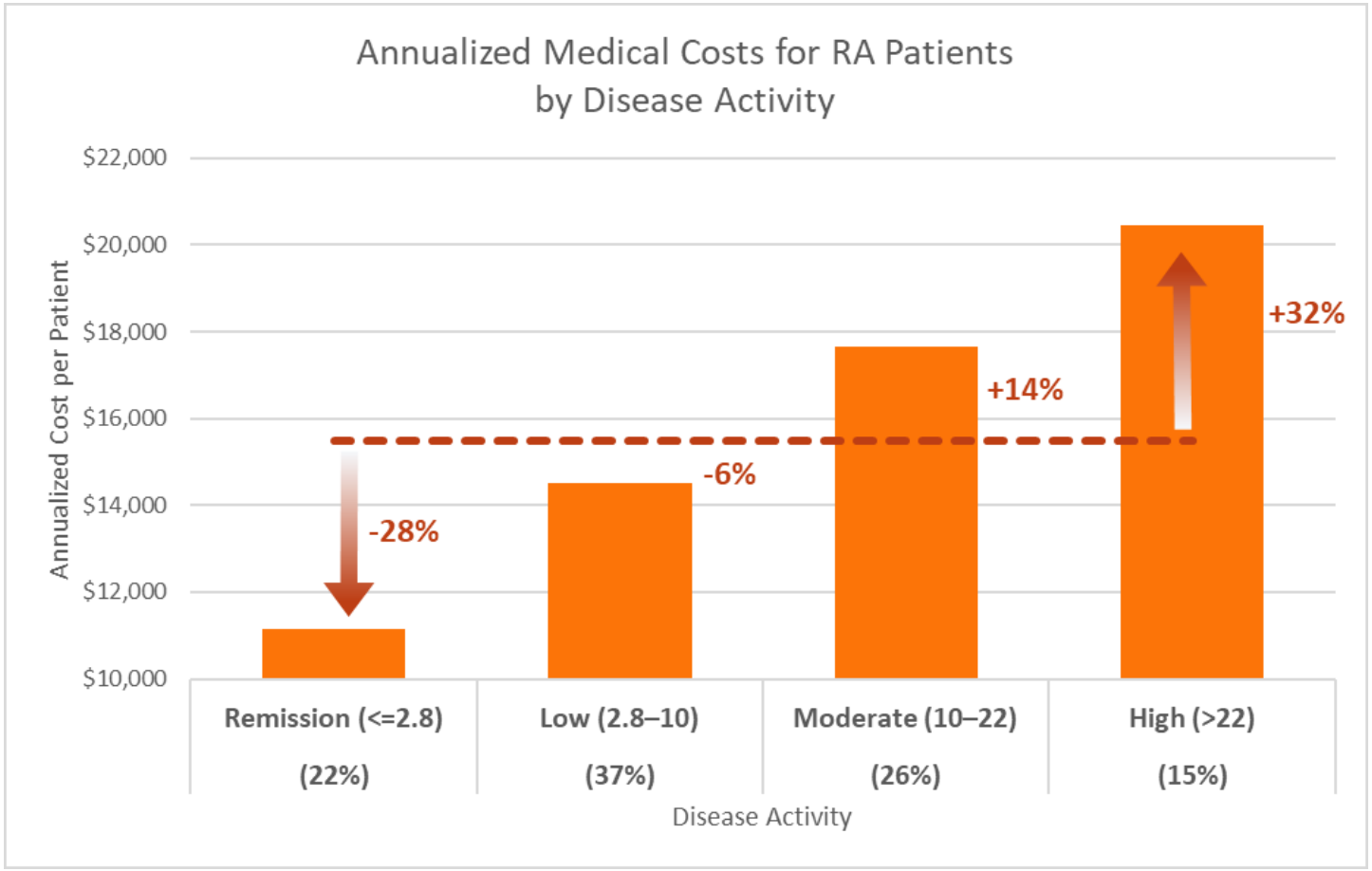
Linking claims data with patient registry data: Healthcare Resource Utilization – Medical Costs

Annualized medical costs per patient were estimated to be $15,485

Annualized medical costs also were correlated with disease activity

Segmenting by clinical measures reveals that:

- 22% of patients – those in remission – accounted for only 16% of costs (28% below average)
- Patients with moderate/high disease activity accounted for 50% of costs (20% above average)
- Patients with moderate/high disease activity had 67% higher costs than patients in remission



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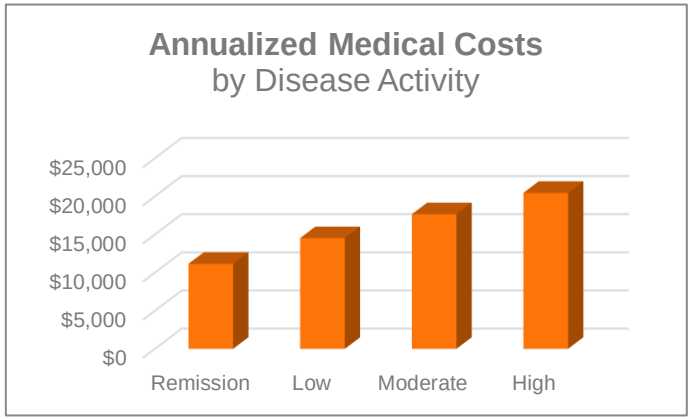
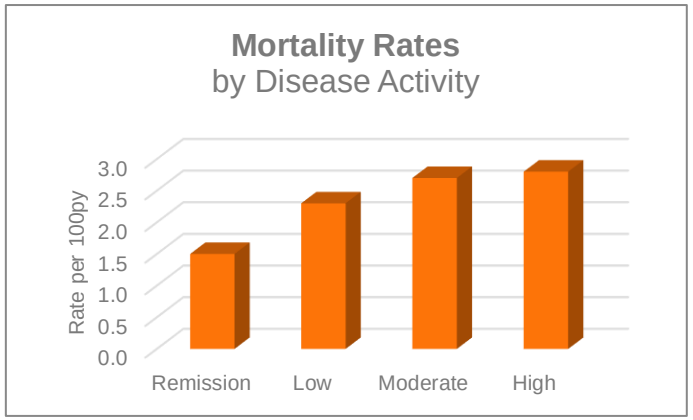
Linking claims data with patient registry data: Healthcare Resource Utilization – Insights

Leveraging the benefits of linking registry and administrative data together, it was demonstrated that lower disease activity in RA was associated with incrementally reduced risks of all-cause hospitalization, ED visits, mortality, and medical costs



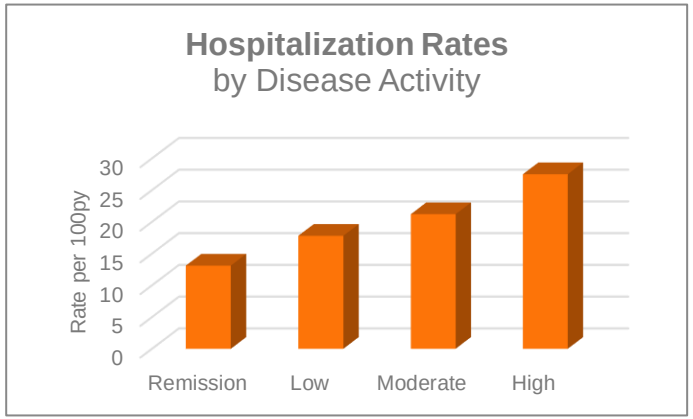


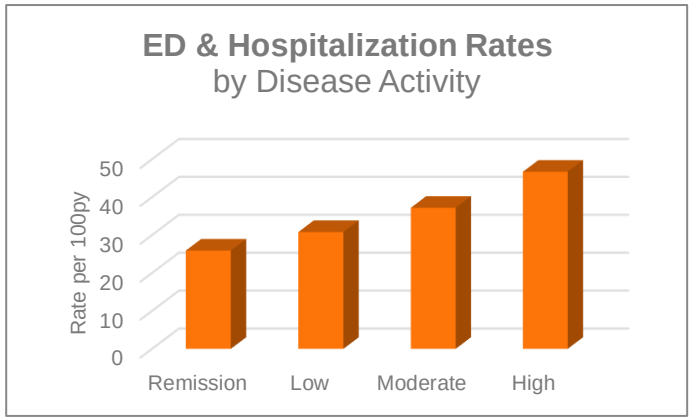
After adjustment for potentially confounding factors, patients in remission and low disease activity consistently had significantly lower event rates compared to patients in moderate disease activity.

Remission was associated with:

- a 32% lower rate of all cause hospitalization
- a 24% lower rate of ED visits/hospitalization
- a 37% lower rate of mortality
- $3133 per year lower healthcare costs

...compared to patients with moderate disease activity





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EXAMPLE USE-CASE:

Deeper Insights into Patient Journey

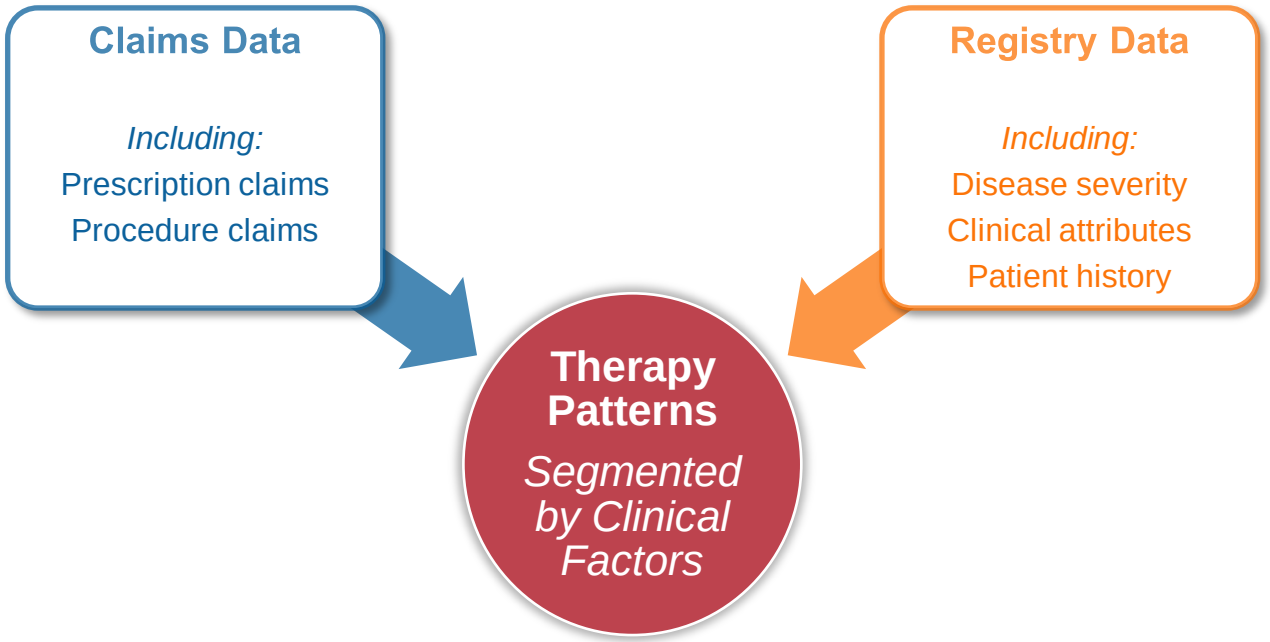
Linking claims data with patient registry data: Insights into Patient Journey

Objective:

To examine the potential influence disease activity may have on patient treatment pathways, among RA patients

- Secondarily, to demonstrate contributions that clinical attributes and patient phenotypes may have on analysis of the patient journey

Data Sources:



Mapping the patient journey can be complex, including steps such as

- Diagnosis
- Initial treatment
- Switching
- Adherence
- Persistence
- Lines of therapy
- Provider encounters

*This analysis focuses on one step in the journey – **switching therapies** – to provide insights into the contributions of clinical factors*

Linking claims data with patient registry data: Insights into Patient Journey – Patient Selection

Cohort:

To be eligible for the linked data analysis, patients must meet the following criteria, across both data sources:

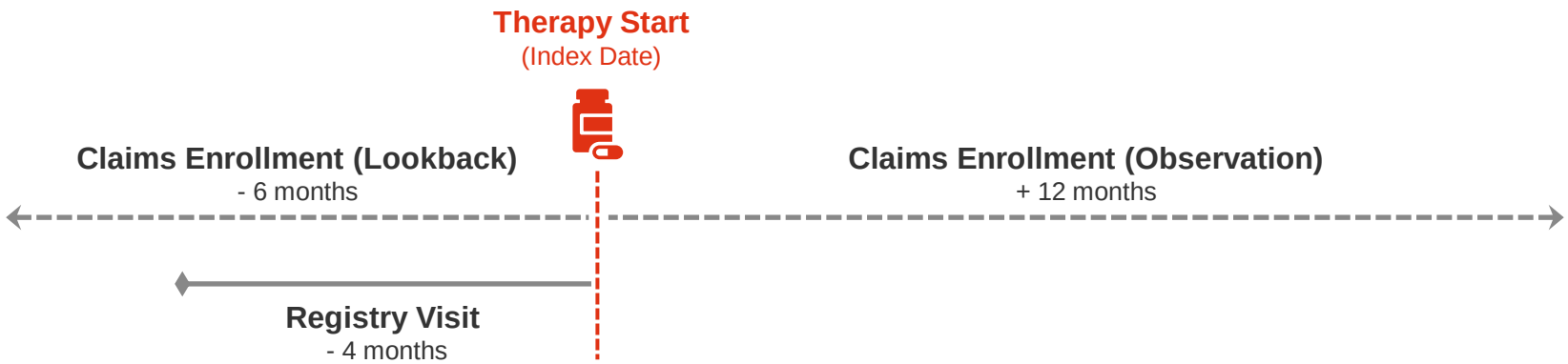
- Anonymized IDs are linkable between the two data sources

From the claims data:

- Enrolled with medical and pharmacy coverage
- Continuous enrollment for 6 months prior to, and 12 months following, therapy start
- No claims for the index drug, within the prior 6 months

From the registry data:

- Have an encounter at a registry site prior to the therapy start date
- Encounter must have occurred within 4 months of (or same day as) the therapy start, in order to associate disease activity with therapy start



Linking claims data with patient registry data: Insights into Patient Journey – Study Metrics

Treatment Metrics
(Claims Data)

- Patients were indexed at initiation of therapy for each b/tsDMARD
  - patients may have been indexed on more than one product during the study period
  - b/tsDMARDs included biologic and targeted synthetic DMARDs, as well as biosimilars
- Patients were observed for 12 months, identifying first fill/administration of a different b/tsDMARD
- Outcome measures
  - switch in therapy
  - time to switch

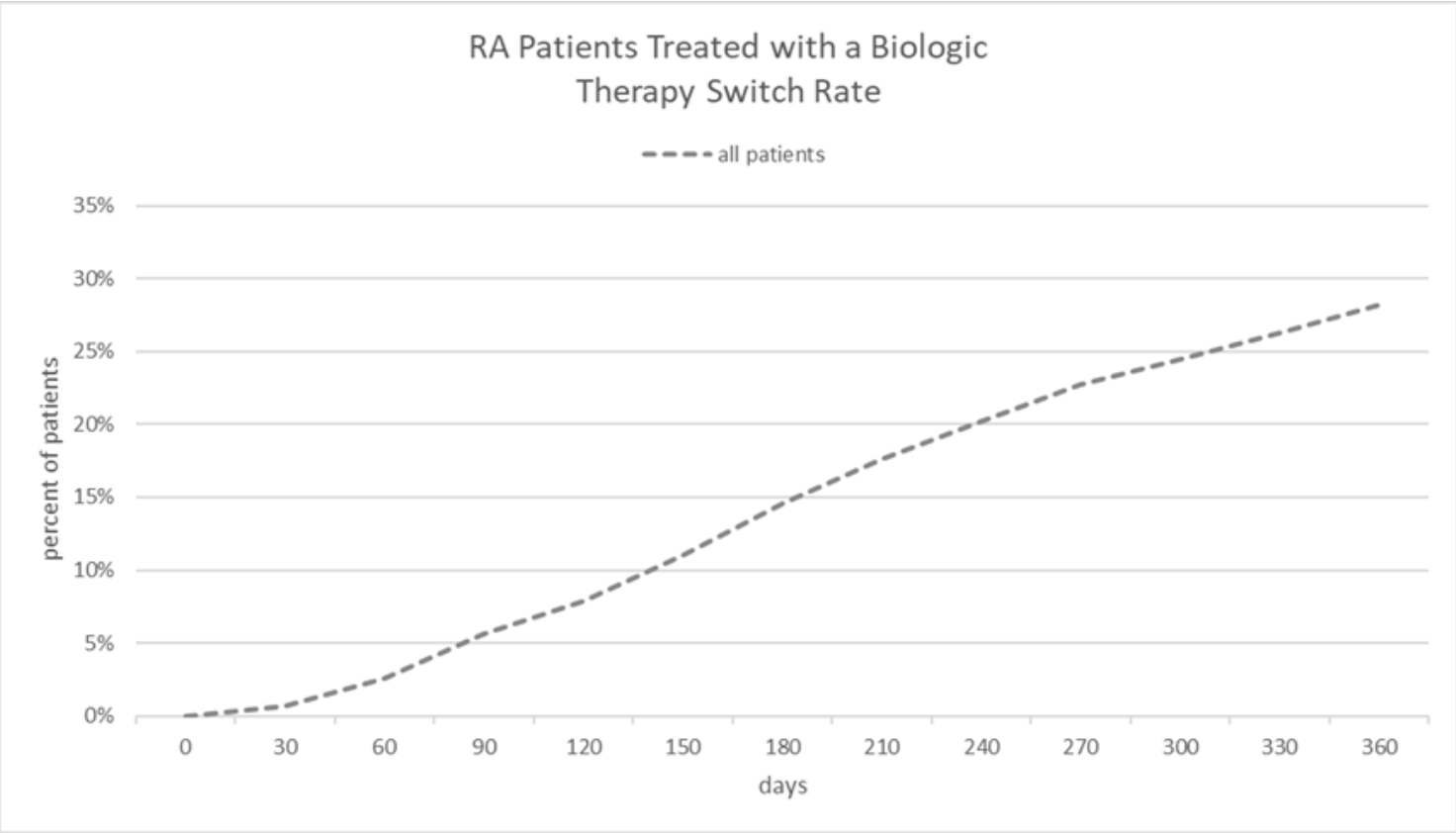
Clinical Metrics
(Registry Data)

- Disease activity measured by the Clinical Disease Activity Index (CDAI) at baseline
  - Remission (<= 2.8)
  - Low (>2.8 – 10)
  - Moderate (>10 – 22)
  - High (>22)
- Patient phenotypes
  - Race and ethnicity
  - Smoking status
  - Education and employment status
  - BMI
- Years since disease onset

Linking claims data with patient registry data: Insights into Patient Journey – Therapy Switches

Exploration of One Step within the Patient Journey:

Switches from one therapy to another



When observed over 12 months, 28% of patients starting on a b/tsDMARD therapy switched to a different therapy

Linking claims data with patient registry data: Insights into Patient Journey – Therapy Switches

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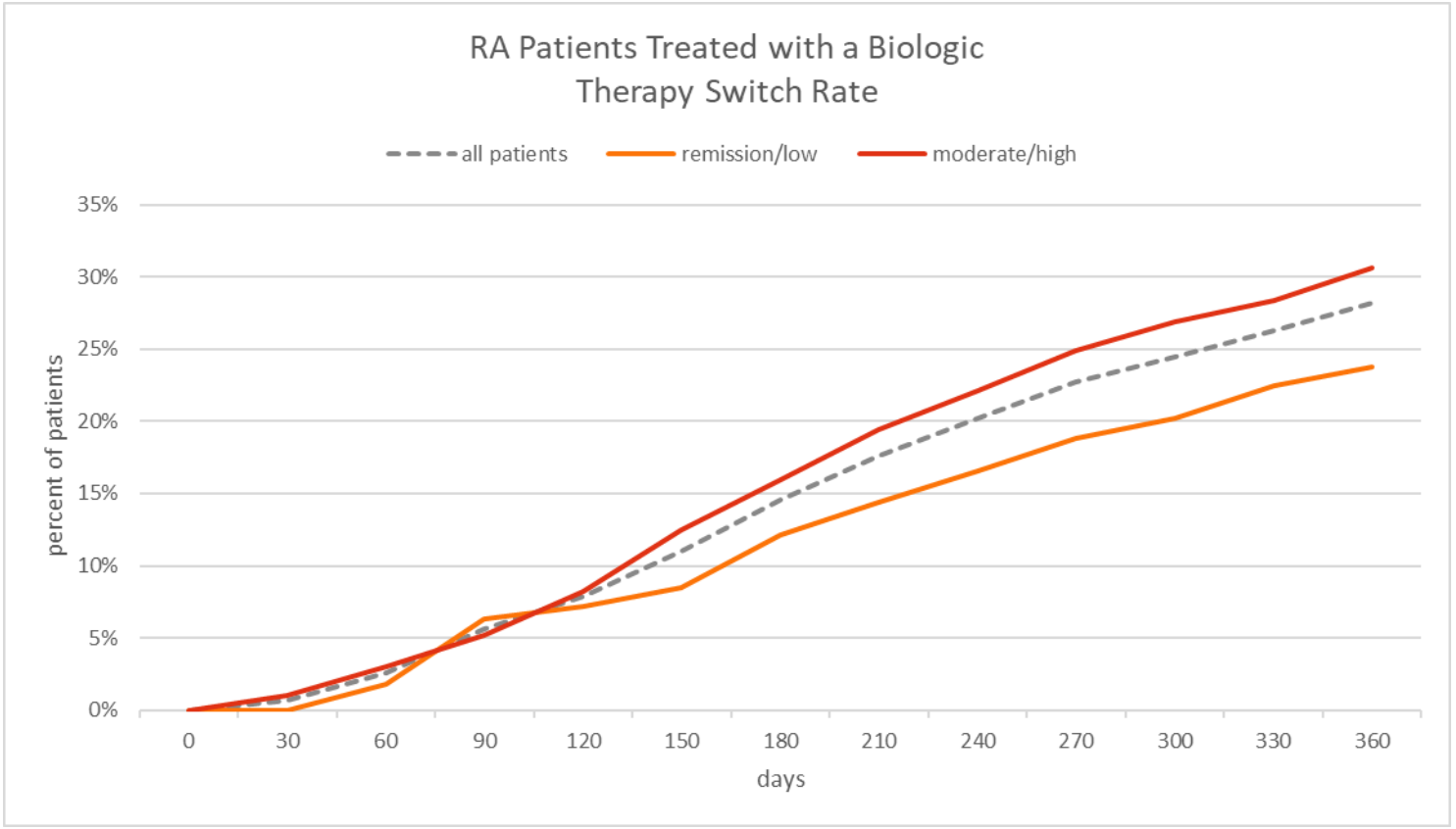


When observed over 12 months, 28% of patients starting on a b/tsDMARD therapy switched to a different therapy

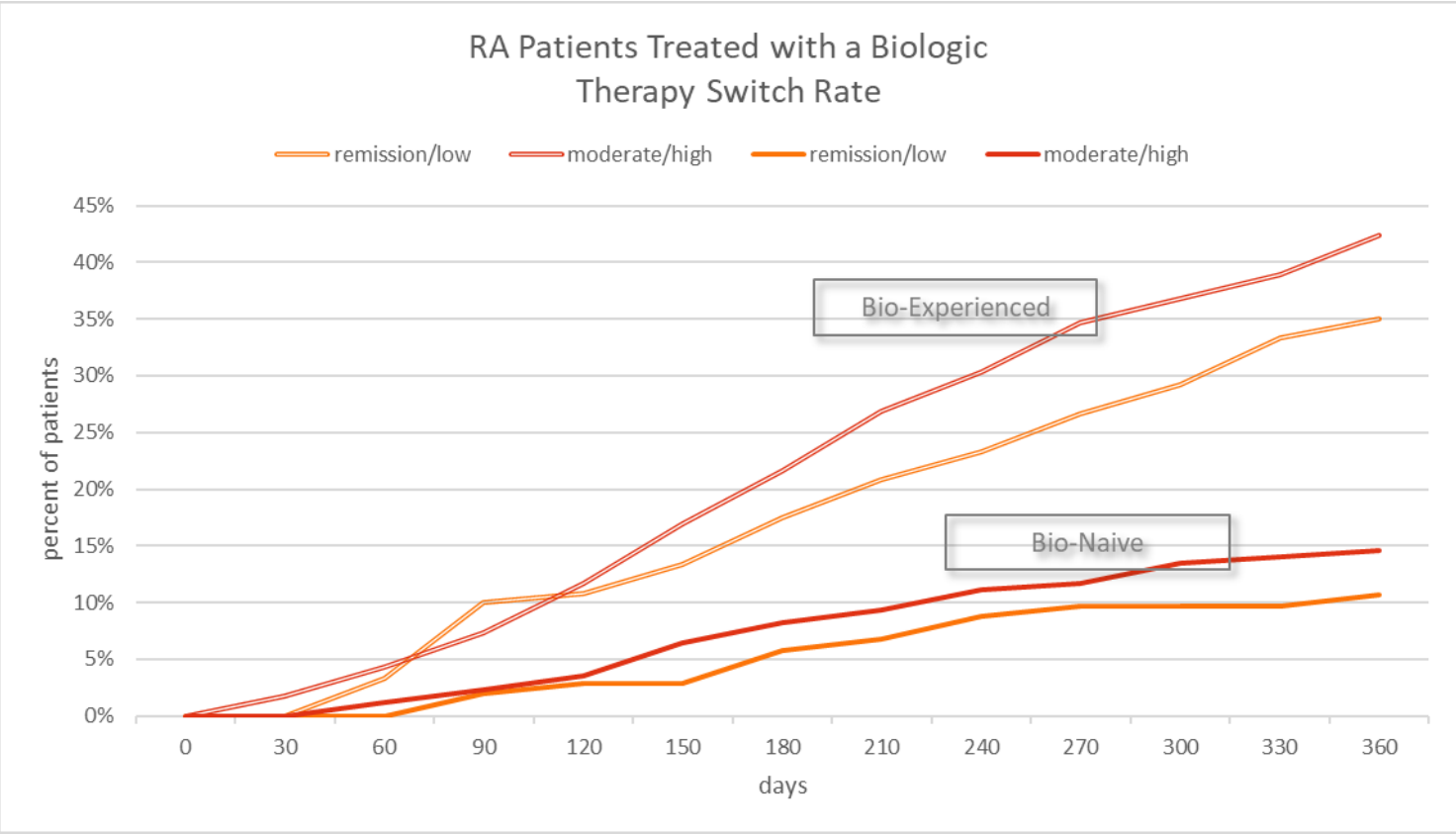
Segmenting by clinical factors shows a difference in switching rates, and time to switch, for patients with varying levels of disease activity

- **Patients with low disease activity at the time of drug initiation were less likely to switch therapies**

Linking claims data with patient registry data: Insights into Patient Journey – Therapy Switches

Exploration of One Step within the Patient Journey:

Switches from one therapy to another



When observed over 12 months, 28% of patients starting on a b/tsDMARD therapy switched to a different therapy

Segmenting by clinical factors shows a difference in switching rates, and time to switch, for patients with varying levels of disease activity

- Patients with low disease activity at the time of drug initiation were less likely to switch therapies

Switching rates also differed for first-line biologic (bio-naïve) users

Summary

Digging Deeper: Uncovering Expanded Patient Insights through Linked Data

In summary...

The ability to link clinically rich data to administrative data sources enables more informed business decisions, with:

- Ability to identify unmet needs in the assessment of patient care
- Deeper insights into association between disease severity, treatment, and outcomes
- Added value and validity of analyses

Potential applications include:

- Support payer discussions and formulary status
- Conduct targeted forecasting by patient phenotypes
- Inform clinical trial design

Poll: How might you leverage linked data for your business questions?

Please use 2-3 words to describe

Questions

THANK YOU!

*Please join us at our reception today at 5pm in **Booth # 610** for further discussion*