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Breaking through the hype of real-world evidence

Utilizing administrative claims data to capitalize on opportunities while avoiding pitfalls

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Given the increasing availability of real-world health data, the development of credible analyses to help fill the knowledge gap between clinical trials and actual clinical practice is more important than ever. In this white paper, we discuss the expanding use of real-world evidence in healthcare decision-making, as well as the importance of clean and reliable data, robust disease identification algorithms, consistent patient attribution methodologies, and relevant outcomes metrics that can be generated from reliably reported data.

What is real-world evidence?

Real-world data (RWD) is data relating to patient health status or the delivery of healthcare collected during the course of clinical care and captured in a variety of data sources, such as administrative claims, electronic health records (EHRs), and product and disease registries.[1] Real-world evidence (RWE) is generated through the analysis and/or synthesis of RWD to identify the effects of health interventions, such as benefits, risks, or resource uses that are not routinely collected during randomized control trials (RCTs). It also can supplement findings about endpoints observed in RCTs by providing information from longer periods of observation or for broader patient populations than those enrolled in the RCT.

Why real-world evidence is important

RWE is key to understanding health-related experience in everyday settings as a complement to other sources of data, such as RCTs. The value of RCTs lies in the random (usually blinded) allocation of patients to treatment or control groups in order to minimize confounders, enabling conclusions to be drawn about the efficacy of the intervention and providing early information about the safety and side-effects. RCTs are considered the gold standard for rational therapeutics in evidence-based medicine. However, RWE allows for the evaluation of new treatments when randomization to placebo may be impossible, impractical, or unethical. Moreover, while RCTs assess whether an intervention works, they are less useful for identifying who will benefit or the cost-effectiveness of different interventions. Miksad observes that recent advances in healthcare have increased the complexity of care and widened the gap between RCT results and the evidence needed for real-world clinical decisions.[2] RWE can help to fill these knowledge gaps.

RWD can be used to provide insight into real-world experiences, including:

- Identifying disease or treatment characteristics of populations, existing patterns of care, and the burden of disease in order to understand unmet needs
- Assessing the safety of new and current therapies
- Providing evidence of relative clinical effectiveness or cost-effectiveness of treatments, including for subpopulations
- Identifying prescribing and adherence patterns of pharmacological products

Stakeholders seek to use RWE for reasons that are specific to their own roles in healthcare innovation and decision-making. For example, health insurers may use RWE to make determinations about coverage and benefit design for specific medical products or services. Healthcare providers may use RWE to develop evidence-based clinical guidelines, as well as to develop decision

[1] Corrigan-Curay, J., Sacks, L., & Woodcock J. (August 13, 2018). Real-world evidence and real-world data for evaluating drug safety and effectiveness. JAMA. doi:10.1001/jama.2018.10136.

[2] Miksad, R.A. & Abernethy, A.P. (2018). Harnessing the power of real-world evidence (RWE): A checklist to ensure regulatory-grade data quality. Clinical Pharmacology and Therapeutics;103(2):202-205. doi:10.1002/cpt.946.

support tools to guide a patient's clinical care. Medical product developers may use RWE to inform clinical trial design and observational studies that may lead to new treatments or to expanded indications for existing treatments. RWE can provide perspective about the effectiveness of a particular product in everyday clinical settings for specific populations in a way that RCTs—which are strictly controlled, time- and resource-intensive, and limited to shorter timeframes—cannot. Sound analyses are especially important for medical products with significant competition, such as classes of drugs that treat the same medical condition (e.g., heart failure, diabetes). In these cases, RWE may influence health insurers' formularies and benefit design, thereby affecting patients' access to drugs.

Great real-world evidence relies on great data

Ideally, the data used to develop RWE has been thoughtfully scrubbed, linked across the types of claims needed to identify a study population, and contains information germane to the clinical or economic outcomes being assessed. It is important to know the characteristics of a data set in order to put research findings into context. The three most common types of health-related databases, EHRs, registries, and administrative claims, have their strengths and limitations depending on the purpose of the analysis (Figure 1).

FIGURE 1: STRENGTHS AND LIMITATIONS OF COMMON SOURCES OF REAL-WORLD DATA

DATA TYPE	STRENGTHS	LIMITATIONS
EHR	Contemporaneous account of the clinical narrative, providing contextual details and long-term follow-up for outcomes Contain clinical information (e.g., blood pressure, weight) previously only available by medical chart review Systems are commonly used throughout the healthcare industry	Completeness depends on clinician workflow, location, and patient factors Large variety of systems and lack of consistency and interconnectivity between systems makes integration difficult Providers do not typically share EHR data with each other, making it difficult to have access to a continuous snapshot of one patient's care
REGISTRIES	Contain detailed clinical information about certain populations, particularly those with rare diseases Are more likely to capture condition-specific detail not found in other sources due to their specificity to a population Patients in registries have already been identified as having the disease or treatment of interest	Can be limited by small sample sizes Only contain clinical information Format and information in registries is specific to the disease or treatment of interest, making it difficult to combine data from registries of multiple diseases Registries from one organization may not be analogous to registries from another organization, which can make combining them difficult
ADMINISTRATIVE CLAIMS	Represent the routinely billed interactions between insured patients and the healthcare delivery system Contain information on diagnoses, procedures, providers, and pharmaceuticals Contain detailed cost information such as billed amounts, reimbursed amounts, and patient cost-sharing in a standard format Permit examination of the full scope of services that are provided in all sites of care to a population Prevalent throughout the country, allowing for large sample sizes for strong statistical power and understanding of national practice patterns Capture payer costs best, because administrative data directly generates the spending that appears in payers' audited financial statements Highly familiar to healthcare stakeholders, including insurers, providers, and medical product manufacturers	Lack detailed clinical information that is not captured in coding (e.g., cancer stage, disease severity, lab test results) Do not describe the sequence of events during a visit Reflect the insurer's coverage decisions and utilization management, which may differ across insurers Reflect only the patient's experience for the time the patient was enrolled with the insurer, which may yield a sizable group of patients lacking claims for the full, optimal follow-up period To the extent the services are bundled (or capitated, at the extreme), the record for all services provided could be less complete Lag in available information from the time services are provided because claims reflect experience that has been processed by payers and subsequently made available for analysis

Compared to EHR and registry data, administrative claims data offer a valuable combination of costs and information on patients' diagnoses and service usage that can be leveraged for population estimates of important clinical and economic aspects of healthcare. While the potential for claims data as a source of RWE is great, it is crucial that analyses be carefully conducted so that populations, treatments, and outcome metrics are identified as accurately as possible. Each study requires a detailed analysis plan that reflects an understanding of how information from all healthcare settings has been coded on claims and describes how relevant claims-based information will be extracted and synthesized for purposes of exploration or to support or refute the study's hypothesis.

The remainder of this report focuses on key considerations when using administrative claims databases to conduct RWE analyses.

Identifying a study population

ELIGIBILITY CRITERIA

Similar to planning a clinical trial, the first step in designing an administrative claims-based analysis is identifying the eligible population. Beyond the choice of the specific claims data source(s), which may vary based on the availability of the source and patient factors such as age, decisions should ensure that the identified total population (termed the denominator population) is appropriate for the intended analysis. For example, some commercial insurance plan members ages 65 and older may have primary coverage through their employer-sponsored insurance but may also have Medicare Part A. In this instance, the available data source may be limited to employer-sponsored claims. In order to ensure that all of the study population's medical care will be captured in the analysis, one potential course of action would be to eliminate patients with dual coverage from the analysis altogether. Adopting deliberate denominator population data screens that are appropriate for the investigation, such as type and length of coverage, is essential to creating a solid foundation for any analysis.

CLINICAL CONDITIONS OR TREATMENTS

Typically, the next step in generating RWE is identifying those individuals in the denominator population who have specific medical conditions, such as diabetes or heart failure; experience a clinical event of interest, such as a stroke or heart attack; or undergo a specific intervention, such as a surgery or a prescription for a drug. These individuals comprise the study population. Patient selection algorithms commonly rely on diagnoses, services, and/or pharmaceutical criteria that are identified in claims using diagnosis, procedure, or revenue center codes. Use of publicly available disease identification algorithms should be considered, such as the Health Effectiveness Data and Information Set (HEDIS) disease definitions or Medicare's Chronic Conditions Data Warehouse (CCW) condition categories. Depending on the medical condition being studied, available diagnosis codes may not be sufficiently specific to identify patients with particular conditions. Diagnosis codes are also subject to inaccuracy and incomplete reporting, especially if diagnoses do not affect the provider's payment. Moreover, variation in the coding patterns used by different types of providers (e.g., hospitals and physicians) may result in medical conditions being inconsistently reported across claims types.

Using pharmacy criteria to identify a study population presents unique challenges due to the payment rules for drugs under medical and pharmacy benefits. For example, drugs administered by a physician in a hospital setting are typically covered under the patient's medical benefit and may be considered part of a comprehensive service paid as a bundle, such as a hospital outpatient surgery. If an insurer's payment arrangement for the bundled service does not require a specific drug code to be listed on the claim for payment, then charges for such drugs are typically reported under a general pharmacy revenue code without any further detail, making it impossible to identify utilization of a specific drug.

Study population identification algorithms can take into account the timing, frequency, or claims type (e.g., inpatient or outpatient facility) where relevant codes are reported. Selection of the most appropriate algorithm depends on the condition-specific balance between identifying as many cases of a condition as possible and identifying cases of the condition with greater certainty. A broader algorithm can identify many cases of the disease at a higher risk of including false positives that do not have the disease (high sensitivity), while a more restrictive algorithm can identify fewer false positives but a higher rate of false negatives, therefore missing the identification of patients who do have the condition (high specificity).

In a study of different claims-based algorithms for several chronic medical conditions, researchers found that using either diagnostic or pharmacy criteria to identify cases, or longer periods of time to capture claims that list diagnoses for chronic conditions or medications, improves sensitivity.[3] In contrast, requiring that a diagnosis is listed on a claim for a face-to-face physician encounter, requiring both a provider claim that lists the diagnosis and a pharmacy claim for a medication commonly used to treat the condition of interest, or requiring at least two claims with different dates of service that list the diagnosis of interest improves specificity. For many practical applications, preferred algorithms have high specificity and as high a sensitivity as

[3] Rector, T.S., Wickstrom, S.L., Shah, M. et al. (2004). Specificity and sensitivity of claims-based algorithms for identifying members of Medicare+Choice health plans that have chronic medical conditions. Health Services Research;39(6 Pt 1):1839-1858. doi:10.1111/j.1475-6773.2004.00321.x.

possible in order to both identify as many cases for study as is feasible and to minimize the selection bias that can occur when cases are identified using algorithms with low sensitivity.

The totality of these initial study design decisions to identify a study population yields an intentional process that filters the total claims data population step-by-step to derive the final study population. The results from each step are typically summarized in a "waterfall" exhibit (as shown in Figure 2), which shows the cumulative effect of the data screens and selection criteria on the starting population.

FIGURE 2: SAMPLE "WATERFALL" EXHIBIT, HYPOTHETICAL ANALYSIS OF THE ADULT POPULATION UNDER 65 SPANNING 2014 THROUGH 2016

DATA CRITERIA	RECORD COUNT
Starting data source population	44,900,000
Data quality screens (e.g., missing member identification numbers, duplicate records)	44,000,000
Continuous medical coverage (January 2013-January 2016)	11,800,000
Age of member < 65 years old as of December 2016	10,750,000
DENOMINATOR POPULATION: Age of member 18+ years old as of January 2014	8,300,000
Confirmed medical condition in index year (2014)	35,000
No indication of diagnosis or treatment for medical condition in the year prior	10,000
STUDY POPULATION: Patient receiving treatment for medical condition within 90 days of diagnosis	5,700

Outcome metrics: Generating RWE

Once a study population is identified, claims data can generate useful information about patient experiences and outcomes that have meaningful implications for patients and healthcare decision-makers. With claims, it's possible to conduct a comparative analysis of the outcomes for subpopulations based on age, gender, and other factors that may contribute to a fuller understanding of disease patterns and targeting of treatments. Claims also allow for comparison of outcomes and costs among treatments to evaluate their relative cost-effectiveness.

Common outcomes from claims data analyses include disease incidence and prevalence, healthcare utilization, and costs. Discrete metrics are frequently combined to present a full picture, such as a comprehensive disease-specific patient journey that may include information about healthcare conditions and disability, treatment patterns, and related healthcare costs prior to and over the years following an initial disease diagnosis.[4,5] We describe some of the methodological issues that must be addressed to develop common RWE metrics from claims data; in particular those aggregated from multiple contributors.

DISEASE INCIDENCE AND PREVALENCE

Only administrative disease prevalence or incidence can be determined from claims data, not true population prevalence/incidence, because claims only include data on healthcare encounters from individuals seeking care. The criteria for defining a disease must first be specified before disease prevalence can be estimated. For serious conditions that almost always require medical treatment at some point in the course of illness, such as congestive heart failure or lung cancer, administrative prevalence will be close to population prevalence.

Following the identification of prevalent cases in a given year, incident cases may be determined by excluding individuals with documentation of specific diagnoses or treatments in a preceding time period. Claims data, however, do not allow for assessing lifetime incidence due to the limited time span of available claims for a given individual. An individual's insurer is likely to change over time, as are the specific database contributors of claims being analyzed. To get close to a population incidence estimate, the disease-free interval should be as long as possible. The length of the disease-free interval for incidence estimation and the degree of limitation from the lack of lifetime data depend on the respective disease and its trajectory.

ADDITIONAL DIAGNOSES

Diagnosis codes on claims can provide information about changes in disease severity, comorbidities that may affect the appropriateness or expected efficacy of different treatments, other conditions that develop during the disease's trajectory, and complications of treatment that may be related to drug safety or other factors. Because these codes are reported on claims for specific dates of services, their appearance also provides information about the timing of the additional diagnoses. As described previously, diagnosis codes have significant limitations due to inaccurate and/or incomplete reporting, even if specific codes for conditions of interest exist. Moreover, the standard set of diagnosis codes—International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM)—contains more than 70,000 codes. Either specific codes must be selected for analysis or the whole set of diagnosis codes must be grouped into condition categories to allow for meaningful interpretation of the findings.

[4] Pyenson, B., Sawhney, T.G., Berrios, M., & Tomicki, S. (April 5, 2017). New Perspectives on the Patient Journey: Real-World Analysis of Prescription Drug Use and Costs in Medicare Part D. Milliman Client Report. Retrieved December 4, 2018, from http://www.milliman.com/uploadedFiles/insight/2017/ms-new-persepctives.pdf.

5 Dieguez, G., Ferro, C., Pyenson, B.S. (April 11, 2017). A Multi-Year Look at the Cost Burden of Cancer Care. Milliman Research Report. Retrieved December 4, 2018, from http://us.milliman.com/uploadedFiles/insight/2017/cost-burden-cancer-care.pdf.

HEALTHCARE UTILIZATION

Claims are incurred when a patient experiences an interaction with a healthcare provider or facility, so they are a natural source of information for the development of healthcare utilization outcome metrics. The interpretation of healthcare utilization requires a thorough understanding of the medical condition or treatment under study, such as the epidemiology of the disease, the disease or treatment trajectory, common treatment alternatives, frequent comorbidities, and other factors. For example, an inpatient hospitalization for heart failure can be interpreted as an indicator of some combination of the severity of a disease and the failure of outpatient treatment management—in other words, a patient's symptoms could not be sufficiently managed and were severe enough to require an inpatient hospitalization. An increase in cardiologist visits for a patient on a new heart failure drug may reflect increasing disease severity, lack of response to the treatment, or drug toxicity, but it may also represent routine monitoring for patients who have newly initiated treatment with the drug. Because claims data do not contain explicit clinical information (e.g., oxygen saturation or heart rate), the information only provides markers of clinical relevance, which must be interpreted in the context of known information about the condition or treatment under study.

Identifying unique utilization from claims may also require detailed algorithms. For example, claims data are organized around billing events rather than actual visits and several visits may be submitted on one claim. The visits must be separated by date of service so the actual number of visits is not undercounted. In addition, multiple claims for a single visit must be identified and combined to remove duplicates that represent errors, otherwise the visits will be overcounted.

The rate of hospitalizations, hospital readmissions, emergency room (ER) visits, or physician office visits are common utilization-based outcomes of interest in studies that assess disease burden or consequences of specific treatments. They are typically identified by the presence of codes indicating the visit type following other claims that indicate the disease or treatment regimen. Certain utilization outcomes also require more sophisticated algorithms. For example, calculating 30-day readmission rates requires implementing logic to look for readmissions within a certain timeframe after the initial hospitalization, as well as accounting for transfers, interim billing, or multiple admissions within the timeframe.

DRUG ADHERENCE

In light of the charge in the 21st Century Cures Act for the U.S. Food and Drug Administration (FDA) to develop a program to evaluate the use of RWE to support approval for new indications for drugs, drug utilization and/or adherence are common metrics in RWE analyses.[6] Drug adherence provides valuable information on the relationship between drug treatment and disease progression, complications of treatment, changes in medication, or healthcare utilization among populations with different characteristics. Drug adherence is defined by the presence of pharmaceutical codes on claims for a specific drug for a specified amount of time. For example, adherence could be defined as a drug's initial injection during a physician office visit followed by 12 months of filled 30-day prescriptions for the self-administered version of the drug. Complicating the analysis of pharmacy claims, prescriptions for drugs may vary in dosage and days supplied (two-week, 30-day, 90-day, etc.), which means that algorithms have to account for continuous coverage by assessing the time elapsed between claims and the dosage/days supply of each claim. In particular, these differences may present challenges when calculating adherence metrics, including medication possession ratio (MPR), proportion of days covered (PDC), and persistency. Another limitation of using pharmacy claims to measure adherence is that claims only reflect whether the prescription was filled, not whether the patient took the medication. Nevertheless, credible algorithms to identify drug utilization and adherence can be developed in most cases, as long as the study's analysis plan reflects a comprehensive understanding of the drug, its uses, and how the claims for the drug appear in the data.

MORTALITY

Death can be determined in a few ways in claims databases. Death in the hospital can usually be identified by a discharge status code on facility claims. Additionally, some claims data sources, such as Medicare Limited Data Set (LDS) files, include date of death for its beneficiaries. However, cause of death usually cannot be identified in claims data as it is not a field that is typically included.

COSTS

Claims data are frequently used to assess the cost-effectiveness of treatments or the financial burden of diseases, in part because of the availability of detailed diagnosis and procedure information associated with these costs. Typically, claims provide line-item charges and allowed amounts for each service documented by procedure codes and include other information such as the date and place of service. This allows for the possibility of associating costs with certain types of care based on the presence of certain codes. Furthermore, the purpose of claims is to provide a record of healthcare services for billing and payment. Cost data from claims therefore reflect a level of accuracy about the paid care the patient actually received that would be less reliable from another data source, such as a survey.

[6] The full text of the 21st Century Cures Act is available at https://www.congress.gov/bill/114th-congress/house-bill/34/. Research;39(6 Pt 1):1839-1858. doi:10.1111/j.1475-6773.2004.00321.x.

With multiple data contributors, it is important to recognize that costs from commercial and Medicare Advantage (MA) claims data represent provider-contracted rates across various health plans. Therefore, when analyzing average costs in commercial and MA claims data, those costs may vary by region, health plan, provider group, and other factors that are unrelated to healthcare utilization. However, spending is often viewed as a proxy for utilization. In some cases, a standardization methodology can be applied to payments that reduces variation caused by these factors. These adjusted spending metrics can be used to make comparisons of the costs of service use.

When assessing costs in claims data, it is important to ensure that the data is clean and accounts for common occurrences in billing. For instance, a single service may be reported on a claim that is submitted, reversed due to an error or change, and re-billed. Each of these steps may be included in the data source as a separate claim. For inpatient admissions, interim billing may occur when a facility submits more than one bill for an individual admission. It is important to ensure that costs in these claims are appropriately "collapsed" so that claims costs and utilization are not double-counted.

Once costs are identified, the results must be presented in a way that is meaningful to interested stakeholders based on how categories of services are provided and paid. For instance, hospitals typically receive a single facility payment from the Centers for Medicare and Medicaid Services (CMS) for the whole inpatient stay for a Medicare patient, regardless of the length of stay, so a cost-per-hospitalization is a straightforward metric. The cost-per-day is front-loaded for most hospital admissions and the cost-per-day also varies based on the length of stay for a given clinical condition, so comparison of a cost-per-day metric across different medical conditions could be misleading. On the other hand, CMS pays skilled nursing facilities (SNFs) a predetermined daily rate for each day of care following an inpatient hospitalization, so cost-per-day is an intuitive metric for this service category.

TREATMENT PATTERNS

To compare outcomes across different disease treatment patterns in claims data, treatment cohorts must first be identified using algorithms based on disease and treatment characteristics and incorporating relevant clinical guidelines when possible. For example, identifying treatment patterns for patients with cancer may require knowledge of a patient's cancer stage, which is generally not directly available in claims data. This may mean the patient's cancer stage must be estimated based on information about diagnoses and treatments and their relative timing in claims data. Next, the most appropriate treatment length for measurement must be determined, which has become more challenging due to complex treatment regimens for patients receiving overlapping courses of chemotherapy and biologic agents that frequently do not reflect the precise treatment protocols of clinical trials. For instance, the same biologic agent may be administered in both first- and second-line cancer treatment. Other conditions, such as depression, may require different cohort strategies that reflect considerations such as drug continuation, discontinuation, dose escalation, drug combinations, drug augmentation, and drug switching.[7] Once the disease treatment patterns are identified, utilization and cost outcomes for the different patterns can be assessed.

RISK ADJUSTMENT

Effective comparison across cohorts requires some degree of risk adjustment to account for differences in the general health status of each population. Such adjustment, as with all metrics discussed previously, is limited to information available in the administrative claims data. There are a number of administrative claims-based methodologies that can be utilized to produce risk scores for each individual that are incorporated into comparative methods such as regression analyses. The U.S. Department of Health and Human Services (HHS) has developed a concurrent risk adjustment algorithm (using the current year of data) for individual and small group commercial markets that can also be used for the commercial market in its entirety.[8]

Similarly, CMS developed a historical risk adjustment model (based on the prior calendar year of data) for MA beneficiaries.[9] Risk adjustment methods may be used to predict costs in the future, where costs serve as a proxy for patient health status for purposes of analysis. Regardless of how cohorts are risk-adjusted, it is important that the method is consistent across cohorts and aims to adjust for factors that can bias the comparison of interest.

[7] Fitch, K., Iwasaki, K., & Pyenson, B. (December 4, 2012). An Actuarial Analysis of Treatment Resistance in Patients With Major Depressive Disorder in a Commercially Insured Population. Milliman Client Report. Retrieved December 4, 2018, from http://www.milliman.com/uploadedFiles/insight/health-published/pdfs/actuarial-analysis-depressive-disorders.pdf.

[8] Kautter, J., Pope, G.C., Ingber, M. et al. (2014). The HHS-HCC Risk Adjustment Model for individual and small group markets under the Affordable Care Act. Medicare Medicaid Res Rev.;4(3):mmrr2014-004-03-a03. doi:10.5600/mmrr2014-004-03-a03.

[9] CMS (July 31, 2018). Risk Adjustment. Retrieved December 4, 2018, from https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Risk-Adjustors.html.

RWE: immense potential when done right

As RWE plays an increasingly important role in healthcare decision-making, the translation of RWD into actionable and meaningful evidence requires the use of high-quality data and rigorous, thoughtfully developed analytic methodologies in order to establish confidence in the findings. Figure 3 summarizes the main steps and considerations for conducting these analyses using claims data.

Analyzing claims data to develop RWE requires detailed knowledge of the types of information routinely reported on administrative claims, including relevant diagnosis codes, services, and drugs applicable to the study subject. It also requires an assessment of the balance between the sensitivity and specificity of alternative study population identification algorithms in order to determine the algorithm with the best performance to meet the study objectives. The methodology to assess outcomes must be similarly thorough, appropriate to the RWE of interest, and informed by all available information on the topic. Finally, it is important to present results from these analyses in ways that facilitate accurate interpretation and are meaningful for healthcare decision-makers. While the goal of these analyses is to provide evidence of activities and behaviors in the "real world," users of RWE analyses need to understand the caveats and limitations inherent to the data sources and methodology. When these factors are taken into account, messy data can be translated into sound RWE that fulfills its potential as a "game-changer" in moving decisions away from perceptions and broad extrapolations and toward actual facts about patient journeys and outcomes.

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FIGURE 3: KEY STEPS TO ANALYZING CLAIMS DATA TO DEVELOP CREDIBLE RWE