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ESTABLISHING CORE VALUE CLAIMS FOR HEALTH SYSTEM SUBMISSIONS: SOME CONSIDERATIONS

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ABSTRACT

Health technology assessment (HTA) or pharmacoeconomics occupies a unique position in the sciences and social sciences: it rejects the standards for normal science and fundamental measurement. This is made clear in the focus on assumptions driven lifetime modelled simulations that create approximate imaginary information to support claims for cost-effectiveness. This belief system lacks both truth and epistemic value. Rather than continue with models that are an analytical dead end, we must look to a new start in HTA that recognizes the need to follow the standards of normal science and fundamental measurement. This devolves to a focus on specific value claims, agreed to by the manufacturer and the health system, which are supported by protocols. Central to this focus is to recognize the importance of value claims for anticipated or assumed compliance behavior over the time frame for value claims assessment. Until an agreed or assumed pattern of compliance behavior is in place, value claims for clinical effectiveness, patient reported outcomes (PROs), drug utilization and resource use profiles are impossible. Value claims for persistence with therapy are the basis for value claims for the first 12 months following approval by a health system. This brief introduction considers the importance of benchmarking value claims. To ensure, well before product launch and formulary submission that protocols are developed for value claims to support a new product but in the historical context of the performance of potential comparator products. Value claims, agreed between manufacturer and health system, are contractual obligations. They are designed, not to create imaginary claims, but to set the stage for a research program..

INTRODUCTION

In health technology assessment, the belief system or meme that has held a central place for the post 30 years has endorsed the role of approximate information or imaginary claims for cost-effectiveness [1]. Guidelines for reference case assumption driven simulations have been extensively pursued and implemented on a global scale [2 3]. The result is obvious: HTA reference and similar decision models fail the standards for normal science and fundamental measurement [4]. Non-science has overturned science; the rigors of the scientific revolution of the 17th contrary and the progress in science and the social sciences, the evolution of objective knowledge is deemed irrelevant [5].

This embrace of non-science in unacceptable. Without credible, evaluable and replicable claims for pharmaceutical products and devices, health system decision makers may as well toss a coin

or consult tarot cards to judge the suitability of therapeutic options. The challenge is to reject the current relativist belief system in favor of one that puts empirical evaluations and objective knowledge first and foremost. Certainly, evidence is all too often patch when a new product is considered for formulary placement; but the answer is not to invent evidence to make up gaps, but the establish a research program to support a product over its useful life cycle. This can be achieved by a focus, not on decision models, but on value claims supported by protocols that can be agreed to with health system decision makers and assessed in meaningful time frames. Just as empirical evaluations are provisional, subject to falsification and re-assessment, so formulary pricing and access are provisional subject continuing reassessment as new evidence is presented.

The purpose of this brief note is to provide a framework for developing value claims to support pharmaceutical products and devices through their life cycle, to include disease area and therapeutic class reviews. The value claims, supported by individual assessment protocols must include clinical or physical endpoints, patient reported outcomes, compliance, resource utilization and adverse events. Claims for each must meet the standards for unidimensional, linear, interval and invariant measurement. Compliance plays a critical or foundational role, to establish the target patient population for value claims assessment. Benchmarking is proposed to establish the basis for value claims. Manufacturers must establish the required value claims with protocol development initiated well before seeking marketing approval. The manufacturer must underwrite value claims assessment, contracting to present assessment results in a meaningful, yet short, time frame.

PLANNING A FORMULARY SUBMISSION

In a formulary submission the first part typically centers on presenting pivotal efficacy claims. These claims are grounded in phase III trial data, directly comparing the new therapy against established comparators or the standard of care. Key components of this section include a rigorous description of the study design, patient population, and primary and secondary endpoints, with results highlighted in terms of clinical relevance, statistical significance, and any advantage the new therapy may offer. Detailed subgroup analyses may be provided to address specific patient segments or demonstrate robustness across varied demographics.

In the second part, following the clinical efficacy profile, a reference case simulated model is typically presented. This comprises an assumption driven simulated lifetime Markov model that creates claims for direct medical costs and QALYs over the lifetime of a hypothetical population. This yields cost-per-QALY claims for a hypothetical population, presented in incremental terms against a comparator or notional standard of care. The resulting claims for cost-effectiveness are, by design, not empirically evaluable, lacking both truth and epistemic value.

The proposed new start or paradigm in HTA rejects the creation of assumption driven lifetime simulations in favor of value claims specific to agreed issues to include clinical, PRO, compliance, resource utilization and safety/adverse events. Rather than health system decisions based on so-called modelled approximate information, presenting health system decision makers with feedback from a value claims assessment profile or package that meets both the standards of normal science and fundamental measurement each value claim required to be empirically evaluable within a meaningful timeframe (ideally, 12 months). In other words, we consider issues and challenges in formulating value claims that are both empirically robust and actionable for

formulary decision-making. This involves aligning each value claim with clear, unidimensional constructs, ensuring they are supported by reliable, replicable assessment profiles that reflect real-world patterns in the target population. This approach reinforces the necessity of developing claims that not only fulfill methodological standards but also carry practical relevance in informing healthcare decisions.

Preparing a formulary submission for a new product requires strategic planning and execution well before obtaining marketing approval from the FDA. Manufacturers must proactively identify and articulate the key value propositions of their product to effectively position it within the competitive landscape. This involves establishing compliance standards through clear protocols that outline methodologies for measuring and evaluating each value claim associated with the product. By defining specific benchmarks for efficacy, safety, compliance, and resource utilization, manufacturers create a roadmap for substantiating these claims with empirical evidence.

The role of protocols is crucial in detailing benchmarks for each proposed value claim. For instance, in the context of compliance, protocols can specify adherence rates expected based on historical data from comparable products. This provides a clear target for the product's performance while helping formulary committees understand the criteria for assessment. Furthermore, protocols should outline the data sources, measurement instruments, and statistical analyses used to validate each claim. If a manufacturer intends to use a Rasch instrument to assess patient-reported outcomes, the protocol must detail its implementation, including expected population characteristics and the timeline for data collection and analysis. This transparency enhances the credibility of the submission, demonstrating the manufacturer's commitment to rigorous evaluation processes.

To optimize the formulary submission process, it is essential to utilize efficiently the time spent on protocol development. Everything related to the submission should be in place before the product launch, ensuring that once marketing approval is received, the manufacturer can proceed immediately with its submission. This proactive approach allows manufacturers to streamline their submission processes, avoiding delays that could hinder the product's market entry. By leveraging existing, validated Rasch instruments, manufacturers can expedite their submissions, presenting robust evidence without the need for extensive new protocol development. If a new Rasch instrument is required this can be developed in early Phase 3 with the option of including the instrument in the pivotal clinical trials.

Efficient protocol development not only facilitates quicker submissions but also enhances the clarity and focus of value claims. By integrating established tools into streamlined protocols, manufacturers can present compelling evidence that meets the expectations of formulary committees. This approach allows for a more agile response to formulary requirements, ensuring that the product's value propositions are substantiated effectively without unnecessary delays.

Furthermore, leveraging historical data to set minimum performance criteria can provide a solid basis for evaluating a new product's effectiveness. Instead of solely relying on comparative claims with existing therapies, manufacturers can establish benchmarks based on past performance metrics, setting a standard that the new product must meet or exceed. This method can simplify

the submission process and clarify expectations for formulary committees, as they will have clear, data-driven benchmarks to evaluate the new product against.

Ultimately, the combination of well-defined protocols, established benchmarks, and the strategic use of validated measurement tools creates a compelling case for the new product's inclusion in formularies. By preparing everything ahead of time, manufacturers can capitalize on the momentum generated by marketing approval, facilitating quicker access to patients who stand to benefit from the new therapy. This strategic alignment enhances the product's positioning in an increasingly competitive market, ensuring that the value claims are supported by rigorous, empirical evidence that resonates with healthcare providers and payers alike. In this way, the proactive establishment of protocols and benchmarks not only supports the submission process but also contributes to the overall success and acceptance of the new product in the healthcare landscape.

DEFINING A VALUE CLAIM

A value claim for a pharmaceutical product or device is a credible, evaluable and replicable quantitative measure with unidimensional, linear, interval and invariant properties. A decision to agree a provisional price and tier position will depend upon the extent to which value claims, agreed to by the manufacturer and health care system, are realized in real world practice. Each value claim must, as noted, be accompanied by a protocol that establishes the role for the claim and details how the claim is to be assessed in a meaningful time from product marketing approval and acceptance by the health system. This acceptance is provisional and can occur once the submission has been accepted or it can be delayed until agreed value claims have been empirically assessed. Key to this is that value claims should only be accepted if they can provide feedback in a meaningful time frame such as 12 months for a designated target population.

Value claims can be presented in comparative terms where the reference is the assessed comparator product or in terms of benchmarks taken from literature. Benchmarks are to be preferred as they avoid the time-consuming nature and expense of comparator clinical trials. Focusing value claims on real world evidence trials (as opposed to the unreal world evidence of pivotal phase 3 trials) is all too often a recipe and excuse for never evaluating claims in a meaningful time frame.

As noted, by rejecting reference case decision models, attempts to present value claims in terms of cost-effectiveness must be ignored. Such claims fail the required standards for unidimensionality with linear, interval and invariant properties. The reference case model is simply a waste of time; notably in its insistence on the mathematically impossible QALY. These decision model produce nothing more than imaginary, composite ordinal claims.

An agreed-upon set of therapeutic value claims, supported by rigorously defined protocols, represents a critical step in the alignment between manufacturers and health systems. These value claims form the foundation of expectations for therapeutic performance, allowing both parties to establish clear, measurable outcomes for patient care. Protocols serve as detailed guidelines, outlining how each value claim is to be validated and maintained in real-world settings. They specify the methodological standards for data collection, assessment timeframes, and analytical methods, ensuring the consistency and relevance of the claims within practical healthcare environments. By establishing these protocols in advance, manufacturers and health systems can

prevent ambiguities in measuring outcomes, facilitating reproducibility and confidence in therapeutic claims.

In effect, protocols transform value claims into a contractual framework, safeguarding accountability on both sides. For health systems, the protocols ensure that therapeutic claims are not merely promotional but are empirically supported, reflecting actual patient benefit and resource impact. Manufacturers, in turn, can utilize the protocol-driven claims to demonstrate commitment to quality and transparency, reinforcing trust with health systems. This alignment on protocols also enables efficient updates to value claims based on new data or insights, keeping the contract responsive to evolving healthcare needs. Such a system also allows health systems to incorporate comparative evaluations of competing therapies, helping to optimize clinical and economic outcomes while holding manufacturers accountable for delivering on agreed therapeutic promises.

Finally, value clams have both truth and epistemic value. The recognize the commitment in the sciences and social sciences to the evolution of objective knowledge [6]. It is the failure to recognize the role of scientific inquiry that relegates the current belief system in HTA to irrelevance. Healthcare management decisions must respect both the standards of normal science and fundamental measurement in agreeing to a contract for credible, evaluable and replicable product claims.

TARGET PATIENT POPULATIONS

Defining a target patient population for value claims, particularly those related to compliance and medication possession, requires a nuanced approach to ensure that the outcomes reflect real-world patient experiences. For value claims to hold practical relevance, especially within health system decision-making, the designated patient population must align with both the therapeutic goals and the unique characteristics of patients likely to use the therapy. Here, several considerations become critical, including timing, disease area, baseline health status, and the ability to segment populations when necessary.

Firstly, defining the timeframe within which patients initiate therapy is fundamental. Using a specific, consistent initiation period—such as all patients starting within the first 12 months—allows for clear, actionable insights into compliance and medication possession over time. This timeframe also supports health systems in interpreting the claims as it mirrors a manageable and relevant period for intervention assessment. However, some scenarios may benefit from an even more refined approach, such as monthly cohorts, to capture variations in compliance that may correlate with the initiation period or seasonal factors affecting disease incidence.

Secondly, creating multiple target populations can enhance the utility of value claims by enabling tailored insights for different patient segments within the broader population. For instance, in chronic disease areas like diabetes or heart disease, compliance and medication possession rates can differ significantly across subgroups—such as older adults, patients with comorbid conditions, or newly diagnosed individuals versus those with long-standing disease management experience. Developing value claims specific to these subpopulations allows stakeholders to understand how compliance might vary and adapt interventions accordingly. The ability to segment populations may also reveal critical behavioral patterns and lead to identifying factors that predict better adherence, informing future formulary and therapeutic decision-making.

Furthermore, the identification of core characteristics within a disease area supports this approach. In many therapeutic areas, certain patient attributes—such as age, disease severity, socioeconomic status, and even previous treatment adherence—are known to impact compliance. In a real-world evidence framework, these characteristics become essential to developing value claims that are generalizable and meaningful across settings. For example, understanding that younger populations with specific chronic diseases tend to have lower compliance might suggest the need for tailored adherence programs, while older adults with polypharmacy may face different barriers, such as cognitive or physical limitations. Knowing the core characteristics tied to compliance within each disease area can improve both the design and interpretation of compliance-related claims and ensure their relevance across varying health system contexts.

In defining the target population for compliance and medication possession, it's essential to think beyond a one-size-fits-all model and toward a more dynamic, adaptable framework. This flexibility is particularly valuable when generating real-world evidence, as it allows for claims to be tested and evaluated in a range of populations that reflect the actual patients using the therapy. This approach aligns with health system needs for insights into resource utilization, patient satisfaction, and cost-effectiveness, offering more robust, reliable, and reproducible evidence that speaks directly to diverse real-world patient experiences. By integrating these considerations into the definition of target populations, value claims can be crafted to provide health systems with credible, actionable information that guides formulary decisions and supports the ongoing assessment of therapeutic impact.

HISTORICAL TARGET PATIENT POPULATIONS

Evaluating historical data for target patient populations in existing comparator therapies is invaluable when establishing robust, data-driven value claims for a new product. This approach provides a foundation for defining patient populations based on actual usage patterns and outcomes, reducing the need to start from scratch and enhancing the relevance of the defined populations. By examining compliance, medication possession, and resource utilization across historical cohorts, manufacturers can anticipate potential adherence challenges and identify demographic or clinical characteristics that influence therapeutic outcomes. This data-driven understanding makes it possible to frame target populations more precisely, accommodating known real-world nuances that may impact the new therapy's performance and utilization.

Using historical data also supports manufacturers in formulating realistic, evidence-based value claims early in the development process. For instance, if the historical data indicates that adherence drops significantly within certain patient subgroups (such as patients with multiple comorbidities or those transitioning from acute to chronic treatment phases), manufacturers can account for these patterns by defining specific, targeted patient segments for the new product. This preemptive approach not only strengthens the accuracy of claims regarding compliance and medication possession but also fosters more realistic expectations for health systems. It allows stakeholders to assess the new therapy's potential impact with a nuanced understanding of population-specific performance trends, particularly in comparison to existing therapies.

Moreover, drawing on historical data expedites formulary submission processes by offering well-defined, real-world benchmarks that align with health systems' expectations. Health systems rely

on comparator data to make informed decisions about the added value of a new product. When target populations are grounded in historical evidence, it becomes easier to demonstrate the relevance of value claims, especially if these claims can be directly linked to improvements or distinctions relative to known comparators. This alignment with historical data can facilitate smoother integration of the new product into real-world settings, as the evidence resonates with actual patient experiences rather than theoretical assumptions.

The insights gained from historical data also allow for more efficient trial and post-market evaluations. By adopting target populations that reflect observed characteristics, manufacturers can reduce the likelihood of unanticipated results and refine value claims through a feedback loop grounded in empirical data. This not only strengthens the credibility of compliance and medication possession claims but also supports health systems in interpreting the comparative efficacy, safety, and resource utilization associated with the new therapy. Ultimately, integrating historical data-driven population definitions into value claims makes the entire process more efficient and trustworthy, laying the groundwork for claims that are replicable, meaningful, and actionable across diverse healthcare settings.

DETAILING VALUE CLAIM PROTOCOLS

A protocol supporting a value claim for a new product plays a vital role in demonstrating that the claim is substantiated through structured, evidence-based research. Well-designed protocols provide clear guidelines on data collection, measurement, and analysis, all of which are crucial for substantiating the value claim in a credible, reproducible manner. By establishing the framework for how a claim is to be evaluated, the protocol provides both structure and transparency, ensuring the results are interpretable and aligned with the claim's objectives.

A comprehensive protocol begins with a title and introduction that reflect the focus of the value claim and provide background on the product's intended clinical or real-world application. This introduction should establish the claim’s relevance to patient outcomes or resource use and outline its importance for the product’s positioning. For instance, if the claim is related to improved adherence rates, the introduction should set the context by explaining why adherence is clinically significant in the treatment area and why it is expected to demonstrate the product's comparative advantage. The background also sets the stage for discussing how the value claim addresses potential gaps in current treatments or meets specific needs within healthcare.

The protocol should then clearly define the objectives, with a primary objective directly tied to the value claim and secondary objectives, if any, that support or contextualize the primary goal. The objectives must be specific and measurable. For example, if a claim asserts that the new product leads to a 20% improvement in adherence, then the protocol’s objective is to measure and verify this adherence improvement. This ensures that the primary objective and any supporting claims are operationally defined and can be empirically tested.

The study design and methodology section provide a blueprint for how the research will be conducted. This section describes the approach, whether observational, randomized, retrospective, or prospective, as well as the rationale for choosing this approach. It outlines patient selection criteria, including demographics, clinical characteristics, inclusion/exclusion criteria, and relevant

subgroups. The description of the sample is crucial, as it allows for replication and ensures that results are applicable to the intended population. Further, the protocol should specify the treatment pathway, follow-up durations (such as 6 or 12 months), and the timing for data collection, interim analyses, and final reporting. Each of these elements contributes to a clear understanding of how the study is structured and enables consistent data collection across all stages.

One of the most essential sections of the protocol is the definition of endpoints and outcome measures. These are the specific metrics that will be evaluated to determine whether the value claim holds up against measurable standards. For adherence claims, the protocol may specify adherence rates or persistence metrics such as refill intervals or overall treatment continuation within a set timeframe. Secondary outcomes, such as resource utilization or patient-reported outcomes, can provide additional insights into the claim's impact. The protocol should detail the measurement instruments used, such as validated adherence scales or, if subjective measures are relevant, a Rasch instrument for transforming patient-reported data into a linear measure. This section should tie each endpoint to the claim, ensuring that the value claim is underpinned by specific, credible evidence.

Data sources and collection procedures are also integral to the protocol, specifying how the data will be collected, validated, and managed. Data sources might include electronic health records, pharmacy refill data, and, if relevant, patient or provider surveys. Clearly defined data collection methods ensure that results are consistent, reproducible, and representative of the target population. For protocols relying on real-world evidence, the protocol must specify the timeframe for data collection to ensure it aligns with the anticipated period of product use. Data management plans are necessary for addressing data quality, handling errors, and ensuring that the dataset accurately reflects the study's aims.

The statistical analysis plan outlines the planned analyses, covering statistical models, sample size calculations, power analyses, and methods for handling missing data. This section is central to establishing that the study has the statistical power to detect the expected outcomes. It should detail significance levels, confidence intervals, and any adjustments for multiple comparisons. A clearly defined statistical analysis plan strengthens the reliability of the findings and ensures that the results are interpretable in the context of the value claim. By defining each aspect of the analysis, the protocol preempts possible methodological challenges and maintains consistency in the evaluation process.

To maintain high standards, protocols must also address quality assurance and ethical considerations. This section should describe quality control procedures, such as periodic data audits and checks for protocol compliance. If human participants are involved, ethical approvals from Institutional Review Boards (IRBs) or similar bodies are necessary, along with detailed informed consent procedures. Addressing these elements upfront not only demonstrates that the study is ethically sound but also assures formulary committees and stakeholders that the data is handled responsibly.

Finally, the protocol should outline the reporting process, including when and how results will be shared with formulary committees, payers, and other stakeholders. It should also define the criteria for success for each value claim and clarify how results will be interpreted against these criteria.

This includes describing how findings support or refute the value claim and noting any limitations in the data or methodology that may influence the results.

By developing a protocol that is thorough, specific, and aligned with the value claim's goals, manufacturers ensure that the submission process is smooth, credible, and ready for immediate action once marketing approval is granted. This proactive approach minimizes delays, strengthens the product's positioning, and enables more agile, evidence-based responses to formulary requirements, maximizing the likelihood of successful inclusion and supporting effective patient care. If a formal contractual relationship between the parties is envisaged, well defined protocols will hopefully minimize disputes.

ASSUMPTIONS AND THE PRINCIPLE OF INDUCTION

It has to be emphasized that the commitment to value claims explicitly rejects assumption driven modelled simulations. This is not to deny the potential role of assumptions in short-term, evaluable claims. What is denied is the application of assumptions in claims that extend for decades into the future, producing non-evaluable claims. To understand the role assumption may or may not play we should consider the principle (or problem) of induction.

In *The Problems of Philosophy* Bertrand Russell presented a critical examination of the principle of induction, arguing that it cannot be logically proven or disproven by experience [7]. The principle of induction underpins most scientific and everyday reasoning, as it involves making generalizations based on past observations to predict future events or infer things about unobserved instances. For instance, we see the sun rise every morning and thus assume it will rise again tomorrow. However, Russell pointed out that such inferences rely on the assumption that patterns observed in the past will continue in the future—a belief known as the uniformity of nature. According to Russell, this assumption is unprovable because relying on past experiences to justify future predictions inherently presupposes the validity of induction itself, leading to circular reasoning.

Russell argued that experience alone cannot confirm the uniformity of nature or the principle of induction. Observing repeated patterns or events does not logically ensure that these patterns will persist indefinitely. No matter how many times a particular event has occurred, there is no logical necessity that it must continue to occur. In other words, the future may not resemble the past simply because it has in the past. Attempting to justify the principle of induction by noting that it has "worked" historically only reinforces this circular reasoning, as it uses induction to justify induction, thereby failing to establish a foundational proof for the principle itself.

Since neither logical nor empirical proofs can confirm the principle of induction, Russell suggested that it functions essentially as an unproven axiom—a fundamental assumption we accept without justification. While this assumption underlies much of our scientific understanding and is crucial to making sense of our experiences, it rests on philosophically uncertain ground. The absence of a definitive proof for induction's validity highlights an inherent limitation in our capacity for knowledge, as our most basic reasoning about the future is based on a principle we cannot prove.

Russell's exploration of this "problem of induction" underscores that while induction is highly useful for making predictions and guiding beliefs, it lacks a logical foundation that assures certainty. We continue to rely on induction out of necessity, not because we have definitive evidence that it is reliable. Thus, according to Russell, all inductive inferences are ultimately probabilistic rather than absolutely certain, marking a fundamental challenge to human knowledge that remains unresolved.

CORE VALUE CLAIMS

When a new drug is submitted for approval to a formulary committee, it is essential to establish a core set of minimum standards for value claims that both manufacturers and health systems can agree upon for targeted patient populations. This core set should focus on a limited number of key claims that are relevant, measurable, and clinically meaningful, ensuring clarity and alignment between stakeholders. Note that all value claims are comparative and that protocols for claims assessment must detail the comparator, providing supplementary information on comparator performance.

Core value claims must recognize the constraints imposed by compliance behavior. This means the principal value claim (or claims) must reflect anticipated compliance behavior following the introduction of the product for at least the first 12 months of marketing and product uptake. Options here would include only tracking and reporting on those initiated to therapy in the first 12 months or following everyone initiated to therapy for a minimum of 6 months. This would give a value claims window of 18 months.

There is substantial evidence to support defining value claims for medications based on persistence intervals, particularly when corrected for demographic and other confounding factors. This enhances the reliability of value claims, making them more meaningful for healthcare decision-makers. Evidence demonstrates that persistence with therapy significantly impacts clinical outcomes, resource use, and subjective measures, with these effects often varying over time. Patients with higher persistence with treatments in chronic diseases such as diabetes and hypertension, for instance, generally experience better clinical outcomes, including fewer hospitalizations and improved biomarkers (e.g., HbA1c levels, blood pressure control). Capturing these outcomes at distinct persistence intervals ensures that the product's long-term impact is accurately represented, providing clearer evidence of the therapy's effectiveness over time. Economic analyses also reinforce that persistence influences the intensity and timing of healthcare resource utilization. Patients with longer persistence intervals often incur fewer acute care costs and require less frequent healthcare resources than those with lower persistence.

Additionally, subjective outcomes, such as patient needs and satisfaction with treatment, measured through patient-reported outcomes (PROs) instruments—often developed using Rasch modeling—are closely linked to persistence levels. Evidence shows that patients with sustained persistence tend to report more positive subjective experiences over time, while those with lower persistence often experience declines in quality of life. Thus, tracking subjective outcomes across persistence windows and adjusting for demographic variations helps capture the nuances of a treatment's real-world impact, especially when differences in subjective responses might emerge among different subpopulations.

BENCHMARKING VALUE CLAIMS

Benchmarking provides multiple advantages for supporting value claims beyond the efficiency and focus it offers compared to clinical trials. By relying on established data standards from past studies or real-world datasets, benchmarks create performance criteria that can be used to assess a new product without the lengthy, resource-intensive processes involved in trial-based evidence gathering. This allows benchmarks to function as clear, reliable indicators for assessing product performance on metrics like compliance or resource utilization, where meeting or exceeding historical standards can validate value claims effectively.

The resource efficiency of benchmarking is a key benefit. By using pre-existing data, manufacturers avoid the need for new patient recruitment, extensive data collection, and extended follow-up periods. This efficiency is particularly beneficial in resource utilization studies where direct comparisons to existing benchmarks can yield meaningful insights without the time and financial costs of gathering primary data. In addition to being resource-efficient, benchmarks improve comparability by providing a stable reference standard against which a new product can be assessed. For claims such as compliance, where adherence rates are frequently used, comparing to a benchmark allows for straightforward assessments that avoid the complexities of comparing against heterogeneous trial populations.

Benchmarking also offers the benefit of faster time to market, as it requires fewer data-gathering steps than a new trial, allowing manufacturers to complete formulary submissions and access markets more quickly. When benchmarks are already validated and sourced from real-world data, they streamline the submission process, making it possible for products to reach patients sooner. This is especially advantageous for value claims related to chronic treatments or conditions where healthcare stakeholders expect timely, relevant data to make informed decisions.

A key strength of benchmarking lies in its relevance and external validity, especially since benchmarks are often based on real-world data rather than the controlled conditions of a trial. This approach provides a view of product performance across broader patient populations and diverse healthcare settings, increasing the applicability of the results for formulary committees, payers, and clinical decision-makers who prioritize real-world evidence. Benchmarks rooted in real-world data thus have stronger generalizability than trial data, providing a comprehensive perspective on performance.

Benchmarking is also adaptable, allowing criteria to be modified based on regional, demographic, or system-specific needs. This flexibility is important for addressing varying requirements across markets or payers. While clinical trials are typically designed around specific research questions and rigid study designs, benchmarking permits a tailored approach, offering targeted insights that can align more closely with stakeholders' priorities.

COMPLIANCE VALUE CLAIMS

Compliance value claims are foundational as they measure how consistently patients adhere to the therapy, directly influencing all other claims. Compliance is critical because it impacts a therapy's effectiveness, safety, and economic value; without high compliance, expected benefits may be unattainable in real-world settings. Benchmarks for compliance rates in the indicated population allow stakeholders to assess if the new product promotes adherence better than existing therapies, thus supporting claims of improved outcomes and resource savings.

Persistence and associated compliance measures are, of course, value claims in their own right. If previous research suggests a positive impact of greater persistence and improved adherence this may suggest a value claim that in comparative terms, against compliance benchmarks for a comparator therapy, that a new product may exceed established benchmarks. This would then factor into other value claims.

Compliance is the essential core value claim for a new product because it serves as the foundation for assessing all subsequent claims related to clinical efficacy, resource utilization, and patient-reported outcomes. Without consistent compliance, the expected therapeutic effects cannot be accurately measured, making any value claims about the drug's effectiveness, safety, or cost-efficiency incomplete or unreliable. Compliance shapes the patient experience, influences persistence, and drives real-world outcomes, offering insights into how effectively a treatment performs under typical use. Since compliance impacts the continuity and depth of therapy, it is essential for predicting and verifying other claims over time, allowing stakeholders to reliably attribute observed benefits and costs to the product itself rather than external adherence factors.

Compliance value claims are the critical driver of all other value claims. They set the foundation and boundaries for every aspect of a new therapy's assessed value, from clinical efficacy to cost-effectiveness. Without high compliance, any claims regarding a therapy's effectiveness, patient outcomes, or resource utilization impact are inherently weakened, if not rendered meaningless. Compliance directly dictates the ability of a therapy to produce its intended effects, ensuring that efficacy claims are not merely theoretical but are substantiated in real-world settings. When compliance is low, expected clinical outcomes become unreliable, jeopardizing the core claims of therapeutic benefit and diminishing the credibility of efficacy statements.

BENCHMARKING AND COMPLIANCE

Relying on benchmarks from existing databases to support compliance claims for a new therapy offers both advantages and challenges, especially when considering the limitations imposed by the problem of induction. On the positive side, benchmarks provide an accessible, cost-effective baseline to evaluate anticipated compliance behavior, allowing health systems and manufacturers to establish preliminary expectations without needing to collect entirely new data from scratch. This baseline helps set realistic goals and assess early-stage compliance patterns, offering a comparative foundation for gauging whether the new therapy aligns with or exceeds existing compliance norms. With established benchmarks, both parties gain a standardized reference point, which can be valuable for framing initial discussions around therapeutic impact, enabling a degree of predictability in assessing patient adherence.

However, benchmarks from past data inherently carry limitations due to inductive reasoning's tendency to overlook the unique factors introduced by a new therapy. Assuming that compliance patterns seen with older therapies will accurately predict behavior with a new one requires believing that all relevant conditions will remain stable, or at least change in predictable ways. Yet, introducing a new therapy often disrupts these dynamics, as it may come with characteristics—such as improved efficacy, fewer side effects, or more convenient dosing—that influence patient behavior in ways historical data cannot capture. This disconnect means that relying solely on historical benchmarks risks misrepresenting the new therapy's actual impact on compliance, as these benchmarks were derived from patients potentially facing different motivations or barriers.

Another concern is that benchmarks from existing datasets might not align with the demographic or clinical characteristics of the new therapy's target population. For instance, if the benchmark data were collected from patients using older, less effective therapies, the trends in compliance might be skewed compared to what could be expected with a more patient-centered option. Compliance behavior can be highly sensitive to changes in healthcare policies, reimbursement structures, and even evolving societal trends around medication adherence, all of which can significantly alter patient adherence patterns over time. Thus, relying on historical benchmarks in a dynamic healthcare environment could yield misleading projections.

Achieving a balanced approach to benchmarks requires integrating them with real-time, protocol-driven data collection specific to the new therapy's effects. While benchmarks provide a practical starting point, they should ideally be supplemented with ongoing data on patient adherence to capture the unique influences of the therapy and account for the characteristics of the anticipated patient population. Additionally, setting benchmarks within a flexible framework that allows for periodic recalibration ensures that they reflect up-to-date compliance patterns as new evidence is gathered. By using benchmarks as informative, rather than definitive, guides, this balanced approach provides valuable initial insights while remaining adaptable. This integration of benchmarks with real-world data ensures that compliance assessments remain relevant and evidence-based without

CLINICAL EFFECTIVENESS VALUE CLAIMS

Effectiveness value claims measure the clinical impact of the therapy when taken as intended, such as reducing disease symptoms or progression. Effectiveness is crucial because it determines whether the product delivers tangible health improvements over standard care. Comparing a new product's effectiveness to established benchmarks, such as standard treatment efficacy and effectiveness rates, establishes a credible basis for therapeutic value. These benchmarks allow health systems to evaluate if the product brings meaningful health advancements and is worth adopting, especially if it demonstrates superior outcomes or fills an unmet need.

Focusing on reproduction trials rather than strict replication of pivotal trial results is more practical and insightful, especially given time constraints and the well-documented challenges of mirroring tightly controlled protocol outcomes. Reproduction trials, which adapt efficacy claims to real-world settings, can offer more relevant insights into how a product will perform under typical

usage conditions, providing data that health systems often find more actionable for decision-making.

Pivotal trials are essential for regulatory approval but are conducted under highly controlled environments, often excluding certain patient populations and minimizing variables that could confound efficacy results. Replicating these conditions precisely is challenging and may yield limited additional value in understanding a product's actual impact in diverse patient populations. A high proportion, approaching 50%, cannot replicate pivotal trial results for the same protocol. In contrast, reproduction trials that incorporate real-world variables—such as patient adherence, comorbidities, and broader demographic factors—help to clarify how efficacy claims hold up in everyday clinical practice. This approach aligns more closely with the goals of health systems and payers, who are often concerned with outcomes beyond controlled efficacy, such as resource utilization, patient satisfaction, and cost-effectiveness under real-world conditions.

Integrating real-world evidence (RWE) into submissions with short timelines—often under 12 months—offers a practical approach to providing actionable, data-driven insights that align with health systems' real-world decision-making needs. In this context, traditional efforts to replicate pivotal trial outcomes can be set aside in favor of designing studies that assess relevant, early indicators like compliance and medication possession over a concise timeframe. By focusing on early-stage adherence, manufacturers can generate meaningful evidence that predicts longer-term compliance behavior, without the prolonged data collection or extensive sample sizes typical of conventional trials.

A common approach for pragmatic and timely RWE studies involves using a sample size of around 250 patients, a practical size in many studies aimed at balancing cost and efficiency while maintaining statistical power. Sampling approximately 250 patients, all newly initiated on the therapy, and following them for a period of around four months can yield critical insights into early compliance patterns. Early possession rates—tracked over three to six months, for example—serve as robust indicators of adherence behavior and provide a foundation for estimating the therapy's real-world effectiveness. This setup, while brief, allows manufacturers to offer health systems valuable insights on medication possession that align with the timelines and priorities of formulary decision-makers.

Sampling frames for RWE are designed to support such smaller, efficient samples, provided they are drawn from a representative and inclusive patient pool that reflects the actual target population. Representativeness in RWE is essential for the generalizability of findings, so patients should be selected to capture the diversity of the anticipated treatment population, including variations in demographics, disease severity, and baseline characteristics. By mirroring the real-world population, RWE studies can offer evidence that is both credible and translatable to broad clinical practice without extensive or prolonged trials. Sampling strategies like random or stratified sampling ensure that smaller samples maintain statistical robustness, while hybrid trial designs enable data collection in naturalistic settings, leveraging sources such as electronic health records (EHR) and pharmacy databases to support reliable, cost-effective outcomes measurement.

An important consideration in the design of these RWE studies is whether to include one or more comparators or to rely on benchmarks established from historical data on comparable therapies.

Including a comparator group within the study can be valuable when direct comparison is feasible, particularly in cases where the new therapy belongs to a novel class or addresses a specific gap that is not well-characterized by existing benchmarks. Direct comparisons are useful when specific therapeutic features could significantly impact outcomes like compliance or resource utilization, as they provide a clear, contemporaneous reference point. However, comparator groups can add complexity, expense, and time to the study, which may not always be justified within the shorter timeframe.

In many cases, historical benchmarks may offer a practical alternative that aligns better with the goals of short-term RWE studies. Historical data from comparable therapies provides a basis for comparison that allows manufacturers to gauge the new therapy's performance in relation to established patterns without requiring a concurrent comparator arm. If reliable historical data on compliance, medication possession, or other real-world outcomes exist for therapies with similar characteristics, benchmarks can guide interpretation by serving as a proxy for expected performance in the target patient population. This approach reduces logistical burdens and enhances feasibility, allowing manufacturers to establish meaningful, data-driven expectations for the new therapy within the constraints of the 12-month timeframe. Additionally, benchmarks allow health systems to assess the added value of a new therapy based on real-world experience, using outcomes that align closely with their operational priorities.

A rigorous focus on benchmark-driven evidence, paired with efficient sampling and early outcomes measurement (e.g., PROs), can also enhance the transparency and credibility of the submission process. Health systems increasingly look for clear, reproducible insights into therapy performance in real-world settings, and evidence grounded in well-established benchmarks meets this need. When compliance and medication possession outcomes are presented against historical standards, health systems can more effectively interpret the likely impact of the new therapy, fostering a clearer understanding of its potential benefits and areas for improvement relative to established comparators.

By grounding target population definitions and outcome measures in historical benchmarks, RWE studies using smaller samples and shorter timeframes can yield data that aligns with both clinical and operational priorities. The integration of representative sampling, efficient data collection methods, and rigorous benchmarks allows manufacturers to streamline submissions while providing health systems with credible, actionable insights. This data-centric approach supports faster, more informed decision-making for formulary inclusion, ensuring that the evidence generated reflects the complexities and demands of real-world use without the extensive investment typically required in long-term trials.

RESOURCE UTILIZATION VALUE CLAIMS

Resource utilization claims examine the product's influence on healthcare resources, such as hospitalizations, physician visits, and medication costs. This claim area is vital because it connects the therapy's use to broader economic outcomes, which are central to formulary decisions. Products that reduce resource utilization—by lowering hospital admissions or minimizing emergency visits, for example—are highly valued. By comparing resource utilization metrics against benchmarks for existing treatments, health systems can assess whether the product will

lower or raise the overall cost burden, allowing them to prioritize treatments that improve care efficiency.

When assessing the impact of a new drug on resource and drug use within a health system, standards such as **Current Procedural Terminology (CPT)** and **National Drug Codes (NDC)** are essential. CPT codes are used to track healthcare services, including medical procedures, tests, and therapeutic interventions. These codes help quantify how a new drug influences resource utilization, such as reducing the need for specific medical services or hospital visits. For example, a new drug might reduce the frequency of diagnostic tests or physician consultations coded by CPT, reflecting its impact on resource use.

NDCs provide a standardized way to identify and track medications. The introduction of a new drug can be monitored by comparing the use of older drugs with the NDC codes for those that the new medication replaces or reduces in use. Additionally, NDCs help capture any changes in the prescription of other medications used alongside the new drug, such as those to manage side effects.

The integration of both CPT and NDC codes allows for a comprehensive analysis of how the new drug affects the broader resource landscape within the health system. This approach captures shifts in healthcare delivery, such as reductions in hospital stays or changes in outpatient care, all of which are linked to the introduction of the new drug. Importantly, these claims should be analyzed over a defined reporting period, such as 12 months, to provide meaningful insights. Furthermore, the data must adhere to the principles of unidimensional, linear, interval, and invariant measurement to support valid and reliable comparisons. This ensures that the impact of the new drug on resource utilization and drug use is accurately and systematically reported.

ABANDONING COSTS AS VALUE CLAIMS

Focusing on resource utilization rather than costs in health technology assessments (HTAs) offers a nuanced, universally applicable measure of a therapy's impact, making value claims more meaningful across diverse healthcare settings. Resource utilization encompasses tangible metrics, like hospital days avoided, the reduction in emergency interventions, or fewer required physician visits, all of which directly reflect how a therapy influences patient care and healthcare system demand. Unlike costs, which vary widely due to local reimbursement policies, labor expenses, and economic factors, resource utilization provides a consistent measure that health systems can interpret in their own financial terms. This approach enables health systems to apply their unique costing structures, allowing for accurate budgeting and planning that align with local financial models and priorities.

One major advantage of using resource utilization as a value claim is its resilience to changing economic conditions and policy shifts. Costs can fluctuate significantly, driven by factors such as drug pricing policies, labor market changes, and broader economic pressures. This volatility can make costs an unreliable indicator of value over time, especially in comparative analyses between therapies. In contrast, resource metrics are stable and more reflective of a therapy's intrinsic impact, offering consistency that is valuable for longitudinal studies and international comparisons. By focusing on specific outcomes, such as reduced hospital admissions or shorter

inpatient stays, HTAs gain a level of objectivity and generalizability that purely cost-based metrics often lack.

Furthermore, resource utilization measures enable a clearer evaluation of a therapy's clinical effectiveness and efficiency. Hospital days avoided, for example, provide a direct link to both patient quality of life and system efficiency, making the value of a therapy tangible without needing conversion into currency. This transparency helps health systems better communicate the real-world benefits of a therapy to stakeholders, highlighting how it optimizes system resources rather than appearing solely as a financial expenditure. In doing so, the HTA can prioritize therapies that make the most efficient use of resources, supporting strategic planning and decision-making based on actual system impact rather than potentially inflated or variable cost claims.

Additionally, resource-based value claims reduce the risk of overstating a therapy's value in lower-cost settings or understating it in higher-cost ones. Because costs inherently reflect local economies and healthcare structures, relying on them as benchmarks risks creating misleading comparisons when therapies are evaluated in diverse settings. By centering HTA value claims on utilization, the assessment becomes more equitable and adaptable across healthcare systems. Ultimately, by focusing on how a therapy reduces resource strain, health systems are empowered to make evidence-based decisions tailored to their budgets and priorities, fostering a more rational, universally relevant approach to assessing value in healthcare.

SUBJECTIVE VALUE CLAIMS

Subjective or PRO value claims address the patient's perspective on health outcomes, such as quality of life, symptom relief, and treatment satisfaction. PRO claims are increasingly important as health systems shift toward patient-centered care. These claims allow health systems to see if the new product aligns with patient preferences and well-being standards, complementing traditional clinical outcomes. Comparing PRO outcomes against established benchmarks from similar treatments can validate if the product meaningfully enhances patients' experiences, offering insight into the product's real-world appeal and potential for adherence.

Subjective value claims in healthcare reflect patients' personal experiences or perceptions of how a therapy impacts aspects of their well-being, such as need fulfillment or symptom relief. Unlike objective claims that rely on direct, observable measures (e.g., blood pressure or lab values), subjective claims capture latent constructs—intangible qualities that patients perceive but cannot directly quantify. Capturing these constructs requires specialized measurement approaches to translate subjective assessments into reliable and meaningful outcomes.

The Rasch model, which employs conjoint simultaneous measurement, is uniquely suited for this purpose [8]. This model establishes a structure that integrates item difficulty (how challenging or intense a particular symptom or experience is perceived to be) with patient ability (the capacity or level at which a patient experiences improvement). Through carefully selected items that fit the Rasch model, the model yields a unidimensional, linear, interval and invariant scale that creates a measurement structure for the manifestation of a latent or non-physical attribute.

The Rasch model is foundational for creating instruments that measure subjective claims because it transforms ordinal, subjective responses into an interval measurement scale. This transformation ensures that each increment on the scale represents an equal difference in the underlying latent construct manifestation , allowing comparisons across patients or over time. For example, if the construct is the patient voice and need fulfillment the manifestation of interest, the Rasch model enables each item selected to correspond proportionally to levels of need fulfillment across patients, creating a robust measurement of this otherwise abstract quality.

This measurement structure is particularly important for subjective claims, as it ensures that the observed scores represent a meaningful, linear progression, rather than arbitrary, variable increments. In practical terms, this means that changes or differences in patient-reported scores genuinely reflect differences in the level of the construct being measured, rather than inconsistencies due to the measurement method itself. Conjoint simultaneous measurement thus provides a rigorous framework for capturing complex, patient-reported outcomes in a way that makes subjective claims credible and interpretable.

The high standards of the Rasch model, however, exclude almost all conventional disease-specific scales and commonly used measures such as the quality-adjusted life year (QALY). Disease-specific measures often aggregate multiple attributes into a single score without ensuring a unidimensional structure, and the QALY combines varied health states into a composite measure, which does not meet Rasch's requirement for unidimensional, interval-level measurement. By adhering to the principles of conjoint simultaneous measurement, subjective value claims gain a scientifically sound foundation, ensuring that they accurately reflect the therapy's impact from the patient's perspective, but in a way that is structured, reproducible, and meaningful across diverse patient populations.

ADVERSE EVENT VALUE CLAIMS

Using adverse events (AEs) and safety issues as benchmarks to support value claims in health technology assessment (HTA) has both advantages and disadvantages. On the positive side, adverse events directly impact patient safety and quality of life, making them a powerful component in value claims when comparing new therapies to existing options. Benchmarking adverse events enables clear comparative assessments, as therapies with fewer or less severe AEs can distinguish themselves by offering a better safety profile, thus reducing treatment burden and enhancing patient experience. These improvements can support claims of improved safety and quality, which are often highly relevant to healthcare stakeholders, including patients, providers, and payers.

Furthermore, a favorable safety profile with fewer adverse events can positively influence treatment adherence, as patients are more likely to continue therapies that they find tolerable and safe. This indirectly supports value claims by promoting better compliance, which in turn can lead to improved clinical outcomes and long-term effectiveness. Additionally, a reduction in adverse events can also result in decreased resource utilization, as fewer AEs translate to less frequent hospitalizations, emergency visits, and monitoring requirements. This resource savings offers a measurable benefit for HTA, supporting claims of cost-effectiveness and efficiency by showcasing how a new therapy reduces the demand on healthcare infrastructure and resources.

However, there are significant challenges in using AEs as benchmarks. One major issue is variability across different patient populations. Adverse event rates can vary widely depending on patient demographics, pre-existing conditions, and even geographic factors. This variability limits the transferability of AE benchmarks, as the data from one population or healthcare system may not hold true in another, raising questions about the robustness of safety benchmarks as a universal basis for value claims. Moreover, AE data from clinical trials often fails to capture the full range of adverse events that may emerge in real-world usage. Trials usually involve highly controlled patient populations and exclude certain high-risk individuals, leading to adverse event rates that may not accurately reflect broader patient populations once the therapy is widely available. Real-world evidence, which may reveal additional or more severe AEs, can thus contradict trial-based benchmarks, challenging the reliability of safety claims that rely exclusively on trial data.

Additionally, quantifying and standardizing adverse events can be difficult. Not all adverse events carry the same clinical weight; some may be minor yet frequent, while others are rare but severe. Benchmarking becomes complex as it involves balancing different types of AEs, which may not be directly comparable. Adverse event severity ratings can also be subjective, with clinicians potentially assigning different levels of significance to the same event based on individual judgment. This subjectivity complicates the development of precise and comparable AE benchmarks across therapies.

Another drawback is the potential for an undue focus on safety over efficacy. While a strong safety profile is essential, an overemphasis on adverse events may inadvertently overshadow the primary therapeutic benefits of a treatment. This could lead to an undervaluation of innovative therapies that, while highly effective, might have manageable side effects. Such therapies risk being unfairly assessed if adverse events are weighted too heavily without appropriate consideration of their overall clinical impact.

Despite challenges, value claims in HTA should consider both safety and efficacy data, alongside resource utilization metrics, to create comprehensive, contextually relevant value claims. Balancing these elements ensures that assessments reflect a therapy's real-world value in patient care and healthcare system efficiency.

CONCLUSIONS

If HTA is to be considered a science, then the belief system, focused on simulated model claims, will have to abandoned. This will be a difficult decision as the straightforward task of constructing simple, assumption driven models with no empirically evaluable claims has its obvious attractions; not least as grist for paper mills and marketing instruments. After some 30 years many will, reasonably, ask why the standards for normal science and fundamental measurement, truth and epistemic value, have been ignored. The most obvious answer is that there was a lack of awareness or even understanding of these requirements. Given the thousands involved in the practice of HTA, this global level of ignorance seems unbelievable. One answer, an unsatisfactory one, is to argue for a sociological or relativist position: that simulation models inventing evidence and creating non evaluable claims is just an alternative viewpoint that must be taken seriously and of equal merit. This, of course, avoid the question of epistemic value and the evolution of objective

knowledge. The relativist position denies progress in favor of decision making relying on assumption driven approximate information.

The purpose of this brief note has been to resurrect the standards of normal science and fundamental measurement in the context of credible, evaluable and replicable value claims for therapeutic decision making. The relativist position is an analytical dead end; it denies the relevance of the notion of the evolution of objective knowledge. To achieve this, we must consider and agree value claims, supported by assessment protocols, to provide a necessary empirical input to decision making sufficient to justify provisional pricing and access for target patient populations defined by compliance parameters, reporting in a meaningful timeframe.

This focus on a core compilation of value claims that are each credible, evaluable and replicable, and meet the standard for unidimensional, linear, interval and invariant measurement provides a stark contrast to the lazy and easy way out of creating imaginary and approximate information claims that lack truth and epistemic value. The path forward for HTA is either to stay with the *status quo* as the only subject area, not a discipline, that rejects the required standards for analyzing therapy impacts or to decide, after 30 years, that a new paradigm is the only defensible way forward.

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The case for a new start in HTA has been detailed in a recently issued Certificate Program from the School of Pharmacy, University of Wyoming.

UNIVERSITY OF WYOMING CERTIFICATE PROGRAM

A NEW START IN HEALTH TECHNOLOGY ASSESSMENT

For those who are interested in following up the arguments presented here for Rasch standard patient centric value claims, the recently released on-line University of Wyoming Certificate Program: A New Start in Health Technology Assessment is recommended.

The Certificate Program is in three parts:

- Part I: Required evidentiary standards for product and therapy assessment
- Part II: The failure of approximate modelled information for therapy decisions
- Part III: Formulary submission value claims and protocols for a new start in product evaluation in health system management

The Certificate Program package includes extensive notes (overall for the 14 modules 85,000 words), audiovisual presentations and a short true-false and multiple-choice assessment for each module. The cost of the Certificate Program is $875 USD with 20.5 hours of ACPE credit. For those who do not need ACPE accreditation, the University of Wyoming will provide a Certificate of Completion. Following interest already expressed, for those introducing the proposed new start standards for technology assessment there will be a

program of one- and two-day workshops and on-line seminars to support course development and alternative program structures to meet local needs. There will also be a series of working papers to explore specific aspects of the new start program.

The link to register in the Certificate Program is:
https://www.uwyo.edu/pharmacy/resources/certificate-program-a-new-start-in-healthtechnology-assessment.html

REFERENCES

[1] Langley P. Nothing to Cheer About: Endorsing Imaginary Economic Evaluations and Value Claims with CHEERS 22 [version 1; peer review: 2 approved]. *F1000Research* 2022, **11**:248 (https://doi.org/10.12688/f1000research.109389.1)

[2] Drummond M, Sculpher M, Claxton K et al. Methods for the Economic Evaluation of Health Care Programmes (4th Ed). New York: Oxford University Press, 2015

[3] Husereau D, Drummond M, Augustovski F et al. Consolidated Health Economic Evaluation Reporting Standards 2022 (CHEERS 2022) Statement: Updated Reporting Guidance for Health Economic Evaluations. *ValueHealth* 2022; 25(1):3-9

[4] Pigliucci M. Nonsense on Stilts: How to tell science from bunk. Chicago: University of Chicago Press, 2010

[5] Wootton D. The Invention of Science: A New History of the Scientific Revolution. New York: Harper Collins, 2015

[6] Popper K. Objective Knowledge: A Evolutionary Approach. London: Clarendon Press, 1979

[7] Russell B. The Problems of Philosophy, 1912

[8] Bond T, Yan Z, Heene M. Applying the Rasch Model: Fundamental Measurement in the Human Sciences (4th Ed.) New York: Routledge, 2021