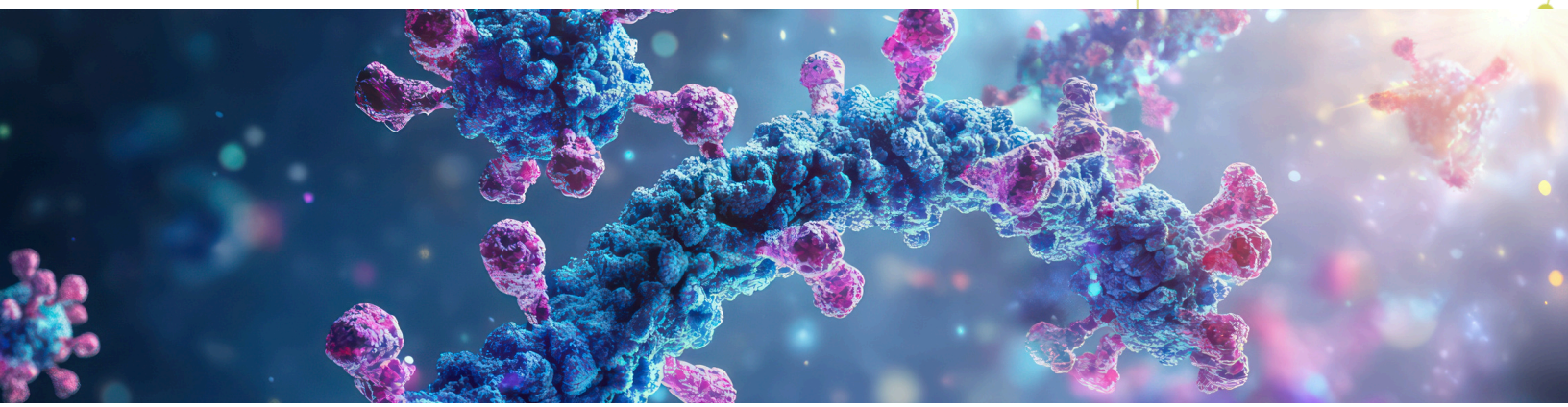
Quanterix®

Discovery Fueled by Ultra-Sensitivity



WHITEPAPER

Proteomics in Transition: From Discovery to Diagnostic Relevance

Introduction

The field of proteomics is undergoing a transition, evolving from its origins in broad discovery proteomics to a new era of clinically focused, targeted proteomics. While discovery methods, such as mass spectrometry, have long served to identify and explore the entire proteome, a new class of technologies is now enabling the precise and reproducible measurement of specific, validated protein targets. Unlike genomics, which provides a static view of predisposition or risk, targeted proteomics captures dynamic, real-time functional biology, reflecting the biochemical reality of disease activity, therapeutic response, and progression in living systems. This shift is transforming proteomics from a retrospective tool into a predictive, diagnostic, and therapeutic asset. Barriers that once hindered clinical translation, such as inadequate sensitivity, poor reproducibility, and workflow complexity, are now being overcome through advances in assay design, platform engineering, and digital detection technologies (Rissin et al., 2010). As a result, the field is entering a phase where proteomics can meet the rigorous demands of both research and clinical practice.

Key drivers accelerating this transformation include:

- Demand for minimally invasive liquid biopsies for early detection and disease monitoring
- Integration of proteomics into multi-omics frameworks to unlock mechanistic insights beyond DNA/RNA
- Pharmaceutical reliance on validated biomarkers for patient stratification and trial design
- Regulatory willingness to adopt biomarker-based endpoints
- Application of AI to interpret high-dimensional proteomic data for diagnostic and therapeutic decision-making

At the forefront of this evolution and transition is Quanterix's Simoa® digital immunoassay technology, which addresses historic limitations by combining femtogram-level sensitivity, high precision, and exceptional reproducibility (Rissin et al., 2010). The platform's single-molecule resolution allows quantification of low-abundance biomarkers, such as phosphorylated tau isoforms, neurofilament light chain, and cytokines that are critical in neurology, oncology, immunology, and beyond. These biomarkers, often undetectable by legacy systems, are now measurable with confidence at physiological baseline levels, a shift that enables earlier detection, trial enrichment, and real-time treatment monitoring (Preische et al., 2019; Palmqvist et al., 2020).

Importantly, Simoa's reliability has been independently verified in more than 3,000 peer-reviewed publications, establishing its reproducibility across different operators, sites, and cohorts (Quanterix Publications Database, 2025).

Unlike platforms that prioritize sensitivity or plex size at the expense of consistency, Simoa delivers clarity and quantification across settings, ensuring that biomarker data retains biological meaning even in complex clinical workflows.

This combination of ultra-sensitivity, precision, reproducibility, and application breadth is unmatched in the proteomics landscape. By enabling robust measurement of biomarkers at the limits of detection, without sacrificing reliability, Simoa elevates proteomics from a supporting role to a core component of clinical innovation. The following sections explore how this transformation is redefining what is possible through proteomics in diagnostics, drug development, and healthcare delivery.

Introduction: From Protein Discovery to Diagnostic Relevance

Proteins are the functional executors of biology, carrying out nearly every task within a cell, from signaling and structure to catalysis and immune surveillance. This functional centrality makes proteins the most direct molecular indicators of disease processes, not merely their predispositions. While genomics and transcriptomics inform on potential or probabilistic risk, proteomics reflects the current physiological state, capturing the consequences of gene expression, environmental exposures, post-translational modifications, and feedback regulation (Aebersold & Mann, 2016).

Despite this, the integration of discovery proteomics into clinical workflows has historically lagged behind genomics.

One reason lies in the sheer complexity of the proteome: protein abundance spans 10+ orders of magnitude, dynamic modifications are ubiquitous, and proteins lack uniform targeting/amplification strategies such as PCR for DNA or RNA. Traditional discovery proteomic tools, such as two-dimensional gel electrophoresis and early mass spectrometry (MS), offered important discovery capabilities but lacked the sensitivity, scalability, and reproducibility required for clinical diagnostics (Bennike et al., 2014; Domon & Aebersold, 2010).

Moreover, protein expression is context-dependent: it varies with tissue type, disease stage, circadian rhythm, and therapeutic exposure. This makes the ability to accurately and reproducibly measure low-abundance proteins in minimally invasive biofluids (e.g., plasma, CSF, saliva) essential for diagnostic applications. Unlike genomic sequencing, which often reveals variants of unknown significance, proteomic measurements can directly map to disease activity and therapeutic effect, offering a faster and more functional readout.

Emerging clinical platforms for targeted proteomics now bridge this gap by achieving femtogram-level sensitivity, allowing detection of key biomarkers that were previously undetectable in accessible matrices. For example, markers of neurodegeneration (e.g., phosphorylated tau and neurofilament light chain), inflammation (e.g., IL-6, IL-17A), and tumor signaling (e.g., EGFR, HER2) are now measurable in blood with high reproducibility, enabling longitudinal disease monitoring, patient stratification, and early intervention (Geyer et al., 2017; Demichev et al., 2020).

Importantly, proteomics is not a replacement for genomics, but rather a critical complement. Integrated multi-omics approaches reveal layers of regulation, where genetic risk may be buffered, amplified, or bypassed at the level of protein expression or function (Hasin et al., 2017). The convergence of these data types is what ultimately fuels a more precise understanding of disease biology. As the biological toolkit expands, proteomics has emerged as the bridge between static genetic predisposition and real-time functional disease activity, making it uniquely positioned to inform diagnosis, monitor

progression, and guide therapeutic response across disciplines. No longer confined to the discovery phase, targeted proteomics has evolved into a mature, clinically operational modality. With next-generation platforms addressing historical technical gaps, and with clinical need growing across neurology, oncology, cardiology, and immunology, proteomics now stands as a translational driver of modern diagnostics.

Historical Context: The Early Proteomics Landscape

The promise of proteomics as a diagnostic tool is not new. Since the early 2000s, researchers have envisioned using protein signatures in biofluids to detect disease earlier, predict prognosis, and guide treatment. However, translating this vision into clinical reality proved elusive for nearly two decades, largely due to limitations in the technologies available to measure proteins with the sensitivity, precision, and reproducibility required for clinical use (Domon & Aebersold, 2010).

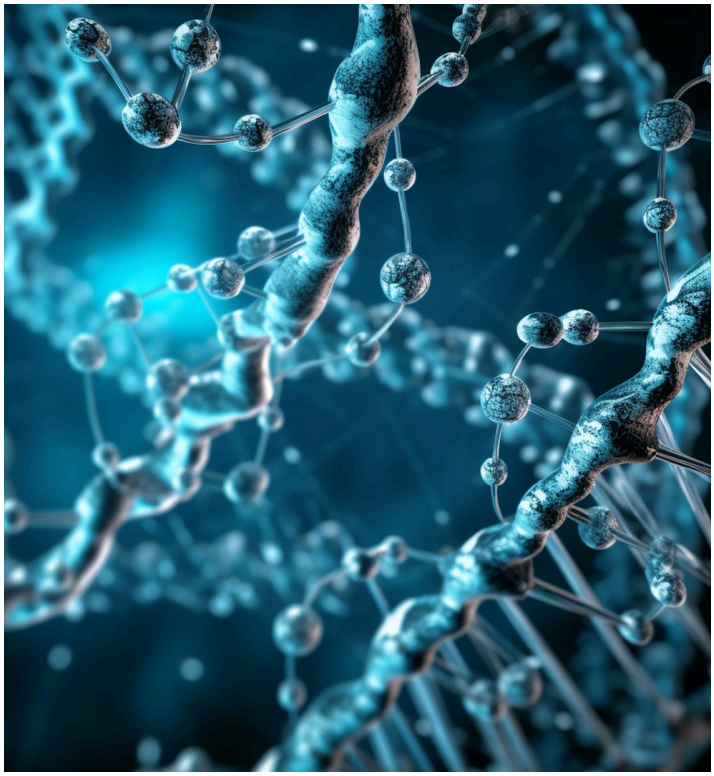
Early targeted proteomic approaches centered on mass spectrometry (MS) and two-dimensional gel electrophoresis (2D-GE). These platforms were powerful for discovery, they enabled the identification of thousands of proteins in complex biological samples, but were poorly suited for clinical translation. They required large sample volumes, extensive sample prep, and costly infrastructure, and were plagued by low throughput, poor reproducibility, and operator-dependent variability (Bennike et al., 2014; Tirumalai et al., 2003). As a result, many early “biomarker discovery” efforts failed to yield clinically validated assays, despite promising discovery-stage findings.

A key example of this translational breakdown can be seen in oncology, where large-scale proteomic studies identified hundreds of potential tumor markers. Yet few, if any, reached FDA approval due to a lack of robust validation in large, longitudinal cohorts. In neurology, similarly, efforts to measure cerebrospinal fluid (CSF) biomarkers such as tau, amyloid-beta, or neurofilament using traditional MS-based or ELISA methods lacked the sensitivity to detect subtle but clinically meaningful changes in early disease (Anderson et al., 2004).

The absence of scalable, reproducible, and sensitive tools led to a bottleneck: discovery proteomics was invaluable for discovery but unreliable for diagnostics. Compounding this was a lack of standardized workflows, harmonized reference materials, and centralized data repositories, which made cross-study comparisons difficult and slowed consensus on validated markers (Rifai et al., 2006).

Nevertheless, these early limitations were not without value. They revealed critical technological gaps, particularly in sensitivity, reproducibility, and multiplexing, that would shape the design goals of the next generation of proteomic platforms.

The turning point came with the advent of digital immunoassays and ultra-sensitive protein detection platforms. These technologies were engineered not just for discovery, but for translational rigor, enabling quantification of low-abundance proteins with unprecedented precision and across large sample cohorts. With their arrival, proteomics began its shift from a scientific aspiration to a clinically viable discipline.



The New Era of Proteomic Technologies

The past decade has ushered in a new era in proteomics, defined not just by expanded protein coverage, but by a transformation in the analytical performance of detection platforms. With improved sensitivity, multiplexing, and throughput, proteomics has moved from hypothesis-generation into true translational application. Yet not all platforms have evolved equally. The clinical potential of proteomics hinges on one central requirement: the ability to detect low-abundance proteins with both sensitivity and reproducibility in real-world sample types like plasma, serum, CSF, urine, and saliva.

Historically, ultra-sensitive detection was constrained by platforms that either (1) lacked sufficient lower limits of detection, or (2) achieved high sensitivity but with nonlinear signal response, poor inter-assay reproducibility, or opaque quantification algorithms (Anderson et al., 2004; Baird et al., 2021). These limitations restricted their use in regulated clinical settings and undermined confidence in cross-cohort comparisons, particularly in large-scale biomarker qualification studies.

Some newer discovery proteomic technologies emphasized high-plex capabilities, measuring hundreds or even thousands of analytes simultaneously. While this offers a broad view of protein expression, it often comes at the cost of quantitative accuracy, with variability introduced through sample dilution, normalization algorithms, and reliance on probabilistic deconvolution models rather than absolute measurements (Kopf et al., 2020). Other technologies pursued sensitivity by applying electro-chemiluminescent signal amplification or rolling circle amplification, but their precision and reproducibility degrade when applied to complex matrices, longitudinal studies, or low-abundance targets near the detection limit (Assarsson et al., 2014).

These technical trade-offs have direct translational consequences. For proteomics to serve as a diagnostic-grade tool, three performance characteristics are essential:

- True ultra-sensitivity, enabling measurement of sub-picogram concentrations of clinically meaningful biomarkers (e.g., pTau217, NfL, IL-6, BD-Tau).
- Quantitative linearity and precision across a broad dynamic range, from femtograms to nanograms per mL, without artificial curve fitting or batch correction.
- Inter-laboratory reproducibility, enabling consistent results across operators, instruments, and sites, essential for clinical trials, and regulatory filings.

Digital immunoassays, particularly those that count proteins at the single-molecule level, have emerged as a foundation for targeted proteomics to address these exact needs. By converting analog immunoassays into digital counting events, they overcome noise limitations, eliminate reliance on bulk signal averaging, and provide absolute quantification with higher signal-to-noise ratios. These platforms also support both single-plex and multiplex formats, allowing users to select only relevant biomarkers while preserving assay integrity.

Critically, next-generation digital proteomics platforms combine ultra-sensitivity with rigorous assay validation, including full transparency of raw data, reference calibrators, and publicly available technical performance metrics. This differentiates them from closed systems that obscure signal derivation or limit access to custom development.

The result is a shift in what proteomics can achieve: not just broader profiling, but actionable, reliable, and scalable biomarker measurement. Today, these tools are supporting diagnostic test development, regulatory submissions, and clinical trial endpoints, solidifying proteomics as a foundational pillar in precision medicine.

The Quanterix Disruption: Ultra-Sensitive Targeted Proteomics Powered by Simoa

The transition from discovery to diagnostics in proteomics has required not only greater sensitivity, but greater clinical applicability. Quanterix's Simoa® (Single Molecule Array) technology represents a disruption not just in analytical performance, but in how proteomics can power real-world decision-making, from drug development to precision diagnostics.

Digital Immunoassay Principles

At the core of Simoa is the transformation of analog immunoassays into digital molecular counting systems. By isolating single immunocomplexes into femtoliter reaction wells and detecting them as binary events (present/absent), Simoa quantifies proteins down to femtogram-per-mL concentrations, far below the detection thresholds of conventional ELISAs or multiplex platforms (Rissin et al., 2010). This results in attomolar sensitivity, a dynamic range spanning 4–5 logs, and low coefficients of variation, even in complex matrices like plasma, CSF, saliva, and urine (Kan et al., 2020).

Precision, Reproducibility, and Translational Performance

Simoa technology enables reproducible quantification across sites, instruments, and timepoints, essential for translational research and regulated applications. Biomarkers such as neurofilament light (NfL), pTau181, pTau217, and BD-Tau have been measured using Simoa in major longitudinal cohorts, showing consistent performance across Alzheimer's disease, multiple sclerosis, ALS, and Parkinson's (Preische et al., 2019; Palmqvist et al., 2020; Janelidze et al., 2022).

Simoa also expands biological accessibility, unlocking molecular insights from tissues and systems that were once difficult to monitor due to physiological barriers, low biomarker abundance, or sample matrix complexity. By enabling detection of proteins at femtogram-per-mL concentrations, Simoa provides researchers with actionable access to molecular signals that previously went undetected in peripheral fluids. A key example is the central nervous system: ultra-sensitive Simoa assays can quantify brain-derived proteins that cross the blood-brain barrier in trace amounts, offering a non-invasive window into neurodegenerative processes.

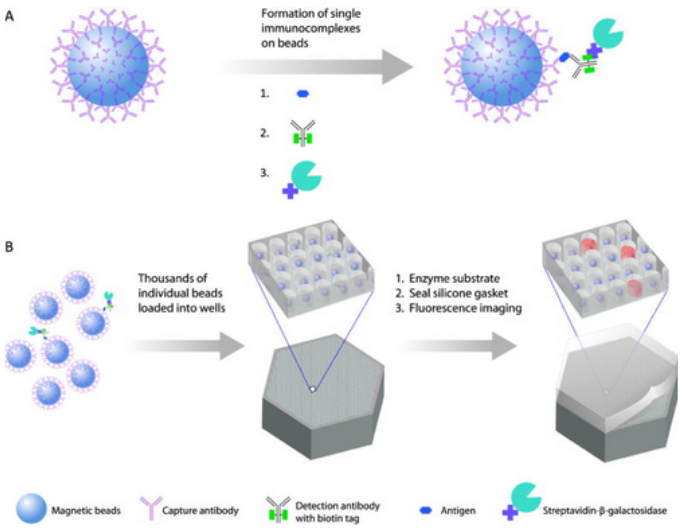


Figure 1. Digital Simoa Workflow for Single-Molecule Detection. Schematic from Rissin et al., 2010 illustrating the two-stage process of Simoa assay execution: (A) formation of immunocomplexes on individual paramagnetic beads; (B) isolation of single beads into femtoliter-sized wells for digital enzyme-based signal detection via fluorescence imaging. This digital approach enables detection of proteins at subfemtomolar concentrations with high precision. Adapted from Rissin et al., 2010. Nature Biotechnology 28, 595–599.

Markers such as BD-Tau and pTau217, now measurable in plasma, enable early detection of Alzheimer's pathology and provide blood-based surrogates for disease staging that were once only possible via cerebrospinal fluid. Moreover, this capability enables fine-grained staging of disease activity: researchers and clinicians can detect temporal shifts in biomarker expression, thereby gauging progression or therapeutic efficacy with far greater granularity than previously possible.

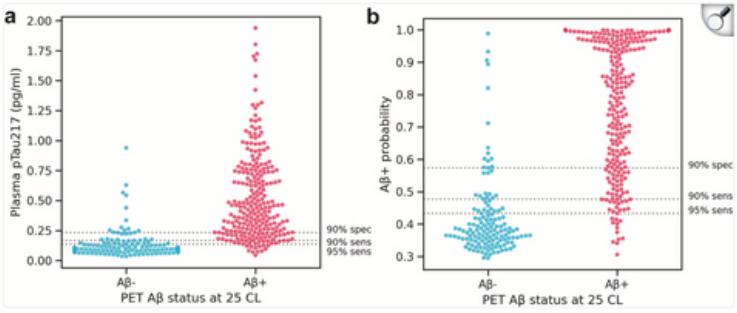


Figure 2. Concordance between plasma p217+tau measured with the Simoa® assay and tau-PET staging. Logistic-regression models demonstrate that higher plasma p217+tau concentrations correspond to advanced biological PET stages defined by ^{18}F-MK6240 tau PET and ^{18}F-NAV4694 amyloid PET. Plasma and PET measures exhibit overlapping diagnostic performance, indicating that blood-based Simoa p217+tau quantification provides information equivalent to tau-PET imaging for Alzheimer's disease staging. Adapted from Feizpour et al., 2025, Communications Medicine

Validated Ecosystem and Development Flexibility

The Simoa HDX platform supports over 100 validated commercial assays spanning neurology, immunology, oncology, cardiology, and infectious diseases. This ecosystem is anchored by rigorous analytical performance, reproducibility across sample types, and translational reach from preclinical studies to clinical trial endpoints (Quanterix Publications Database, 2025).

However, beyond validated kits, the true strength of Simoa lies in its open development architecture. The HDX platform supports homebrew-custom assay development, enabling researchers to adapt and optimize Simoa assays for novel targets, matrices, and study contexts without being constrained by locked-in menus. This open design empowers translational labs to bring emerging or disease-specific biomarkers online rapidly and reproducibly.

A leading example is the widely adopted neurofilament light chain (NfL) assay, originally developed by the University of Basel as a homebrew on the Simoa HD-1 Analyzer. That team demonstrated that serum and CSF NfL levels measured with Simoa correlated strongly with both disease severity and treatment response in multiple sclerosis (Disanto et al., 2017). Their foundational work catalyzed broader interest in NfL as a biomarker, eventually leading to commercial availability of Simoa-based NfL kits and its use in clinical trials for ALS, Alzheimer's disease, and beyond.

Similarly, researchers at the University of Gothenburg used Simoa's homebrew flexibility to build ultrasensitive assays to measure plasma NfL in HIV-associated neurocognitive disorders. Their studies confirmed that subtle CNS injury could be detected through small changes in plasma NfL, supporting the use of Simoa in both clinical and global health research contexts (Gisslén et al., 2016).

Unlike Simoa, many competing platforms, restrict development to predefined panels or vendor-controlled menus. Reagent transparency and user control are often limited, hindering assay innovation for new disease applications or non-traditional matrices such as saliva, dried blood, or urine. Moreover, few alternatives enable rigorous, user-driven validation of femtogram-level assays, narrowing their applicability to early-stage translational research or individualized biomarker strategies.

This balance of validated precision and flexible innovation positions Simoa as both a stable foundation and a forward-looking toolset, uniquely equipped to accelerate the development, validation, and clinical readiness of emerging biomarkers.

A Platform Built for Clinical Translation

Simoa's core technical advantages include full automation ultra-sensitivity, multiplexing, matrix versatility, and data transparency,enabling its adoption across both research and regulated environments. ***But the true disruption lies in its ability to catalyze clinical utility: identifying disease earlier, tracking progression more precisely, and informing therapeutic response in ways previously inaccessible.***

Translating Biomarkers into Clinical Utility: Simoa's Role in Therapeutic Development, Monitoring and Cost Efficiency

The clinical utility of proteomic biomarkers has historically been constrained by technological limitations in sensitivity, reproducibility, and clinical translatability. Recent modeling studies show that biomarker-driven enrichment and digital endpoint technologies can accelerate trial timelines, improve patient targeting, and yield substantial financial returns through shortened recruitment, reduced screen failure rates, and smaller sample sizes (Mori et al., 2022; Inan et al., 2020). The advantages conferred by Simoa, both technical and strategic, mirror these benefits and position the platform as a transformative enabler in modern clinical trial design.

1. Early Detection and Preclinical Risk Stratification

Simoa enables detection of key disease markers, years before clinical symptoms emerge. These biomarkers have been validated across Alzheimer's, ALS, MS, and FTD cohorts as predictors of disease progression and pathology (Janelidze et al., 2022; Preische et al., 2019). This preclinical insight enables:

- Biology-based trial inclusion, rather than symptom-based diagnosis
- Risk stratification in prevention trials
- Early identification of therapeutic windows

Clinical impact: Enhances trial targeting, reduces misclassification, and enables earlier intervention.
Financial advantage: Reduces screening costs and prevents enrollment of non-progressors, helping avoid underpowered or delayed trials (Palmqvist et al., 2023; Mori et al., 2022).

2. Trial Acceleration and Biomarker-Driven Enrichment

Simoa assays support non-invasive, blood-based screening that reduces the reliance on PET imaging or lumbar punctures during eligibility confirmation.

- Plasma BD-Tau and pTau217 have shown high concordance with tau PET, allowing pre-screening without expensive imaging (Palmqvist et al., 2025).
- NfL serves as a progression marker, enabling stratification by risk of clinical decline.

Recent economic analyses demonstrate that platforms enabling efficient biomarker pre-screening can reduce screen failure rates by up to 40% and enrollment timelines by several months (Inan et al., 2020; Mori et al., 2022).

Clinical impact: Improves recruitment efficiency and homogeneity.
Financial advantage: Lowers total cost of enrollment, avoids protocol amendments, and increases statistical power with fewer patients.

3. Pharmacodynamic Monitoring and Adaptive Trial Design

Simoa allows sensitive, real-time tracking of pharmacodynamic biomarkers, supporting early efficacy decisions and adaptive trial approaches:

- NfL decline post-intervention in MS, ALS, and FTD trials correlates with clinical stabilization or slowing.
- Cytokines such as IL-6, IL-17A, and TNF-α reflect immune modulation and therapeutic response.

These real-time biomarker shifts support dose selection, interim analyses, and early futility decisions, allowing sponsors to optimize resources dynamically.

Clinical impact: Enables early detection of response or non-response, reducing risk of late-stage failure.
Financial advantage: Avoids unnecessary continuation of ineffective treatment arms and accelerates go/no-go decision-making.

4. Companion Diagnostic and Reimbursement Enablement

Simoa assays are increasingly evaluated in parallel with therapeutic agents to support companion diagnostic labeling, payer alignment, and personalized treatment pathways.

- In Alzheimer's disease, pTau217 and NfL are under evaluation as diagnostic and treatment-access biomarkers.
- In immunology, cytokine profiles measured via Simoa support patient stratification and response-guided therapy escalation.

Recent policy analyses show that upfront biomarker testing, even when requiring investment, can reduce downstream treatment costs and support value-based reimbursement (Fight Cancer Foundation, 2023; Prostate Cancer Health Economic Review, 2021).

Clinical impact: Supports therapy alignment with biological need and payer expectations.
Financial advantage: Increases ROI per enrolled patient and enables more efficient post-market patient targeting.

Simoa stands as both a scientific disruptor and a strategic enabler. Its analytical power, translational consistency, and infrastructure flexibility combine to improve patient targeting, accelerate therapeutic timelines, reduce operational waste, and lower total trial cost. As leading health economic analyses confirm, the future of clinical trials belongs to platforms that are not only precise, but also operationally efficient and cost-effective. In this landscape, Simoa delivers competitive advantage at molecular scale.

Industry Outlook: The Future of Proteomics and Simoa's Strategic Positioning

The future of targeted proteomics is being shaped not just by market forecasts, but by the accelerating convergence of clinical need, molecular precision, and technological capability. As medicine pivots from population-level generalizations to personalized decision-making, proteomics has emerged as a functional counterpoint to static genomic data, offering temporal insight into real-time disease activity, pathway dysregulation, and therapeutic response. In contrast to genomic assays that capture predisposition, proteomic measurements reflect the dynamic biology of health and disease, making them especially powerful for detecting early-stage pathology, monitoring longitudinal change, and optimizing treatment strategies (Mair et al., 2022; Mathys et al., 2019).

Simoa's integrated capabilities, spanning ultra-sensitivity, multi-matrix validation, global reproducibility, and AI-readiness, position it as a cornerstone of next-generation proteomics.

This evolution depends not only on biological insight but on platforms that can consistently deliver high-fidelity data across a variety of sample types, patient cohorts, and use cases. In an increasingly crowded diagnostic ecosystem, Simoa distinguishes itself by prioritizing quantitative reproducibility and ultra-sensitive detection, even for targets present in sub-picogram-per-milliliter concentrations. While other technologies have chased high multiplexing, often at the expense of precision and analytical consistency, Simoa's approach allows confident quantitation of biomarkers like phosphorylated tau isoforms, GFAP, NfL, IL-17A, and others, both in discovery-phase and clinically regulated settings (Preische et al., 2019; Sato et al., 2021).

Furthermore, artificial intelligence and machine learning are poised to unlock further value from proteomic datasets, but only if those inputs are biologically meaningful and statistically reliable. Simoa data, with its low variability and high sensitivity, supports multi-modal integration with genomic, imaging, and clinical outcome data to power digital biomarker development and AI-enhanced trial design. Recent examples include the incorporation of longitudinal plasma pTau and NfL data into progression models for Alzheimer's disease, which enable earlier identification of patient subgroups likely to benefit from disease-modifying therapies (Karikari et al., 2022; Milà-Alomà et al., 2022).

These advances depend on platforms that generate stable, reproducible molecular measurements across populations and time. Equally important is the shift toward decentralized and point-of-care proteomic testing. Traditional instruments often lack the sensitivity or modularity to operate outside centralized labs, but Simoa's bead-based digital ELISA architecture enables high-fidelity measurement even in novel matrices like saliva, urine, or sweat (Gold et al., 2021; Lin et al., 2022). This opens new clinical and commercial pathways, for example, enabling GFAP-based concussion triage in emergency settings, or IL-6 and TNF-α monitoring in immunotherapy clinics. Future adaptation of the platform for portable or distributed settings will further broaden access to high-quality proteomic data, supporting real-time diagnostics in both routine care and resource-limited environments.

In this landscape, technologies that can combine analytical rigor, clinical versatility, and operational scalability will shape the future of precision medicine. Simoa's integrated capabilities, spanning ultra-sensitivity, multi-matrix validation, global reproducibility, and AI-readiness, position it as a cornerstone of next-generation proteomics. As the field moves from theoretical potential to applied clinical value, platforms like Simoa are transforming what proteomics can achieve and where it can be deployed.

Conclusion: Proteomics, From Discovery to Clinical Impact, Enabled by Simoa

Proteomics has matured from a specialized research discipline into a foundational pillar of translational and clinical science. As researchers seek to decode real-time biological processes and clinicians demand precision tools for diagnosis and monitoring, proteomics now occupies a central role in the continuum from discovery to therapeutic deployment. Whether mapping cellular signaling in early-stage studies or tracking treatment response in real-world patient care, proteomic biomarkers are essential for understanding dynamic biological states.

At each of these stages, Quanterix's Simoa® technology enables deeper insight and greater reliability. While discovery proteomics identifies a broad range of potential biomarkers, targeted proteomics, enabled by Simoa, provides single-molecule sensitivity, capturing low-abundance signals that other platforms routinely miss. Its precision and reproducibility allow researchers to move from exploratory findings to validated biomarkers without switching technologies or sacrificing performance. In translational and clinical contexts, this matters profoundly. A key example is cytokine measurement. For immunotherapy trials and inflammatory disease studies, understanding baseline cytokine levels is critical: it provides a molecular fingerprint of immune activation before treatment, informs stratification of responders versus non-responders, and enables early detection of adverse events. Most legacy and multiplex platforms are insufficiently sensitive to measure cytokines at these low, pre-activation levels, especially in plasma or serum, resulting in data that is truncated, variable, or completely absent. Simoa uniquely addresses this gap, reliably detecting cytokines like IL-6, TNF-α, and IL-17A at physiological baseline concentrations. This capability transforms cytokine assays from blunt, retrospective tools into real-time, predictive instruments for immune modulation.

Competing platforms that prioritize high-plex outputs, common in discovery proteomics often introduce compromises, signal interference, reduced sensitivity, and less reliable quantification, particularly at the lower end of dynamic range. These limitations hinder their utility in patient monitoring, companion diagnostics, and real-world deployment where accurate baseline detection is non-negotiable.

Simoa's high-fidelity, digital quantification maintains biological interpretability across time points and sites, reducing trial noise and improving the power of longitudinal studies. In multi-center trials, this harmonization allows for faster biomarker qualification, regulatory acceptance, and economic efficiency through shorter timelines and better-informed decisions.

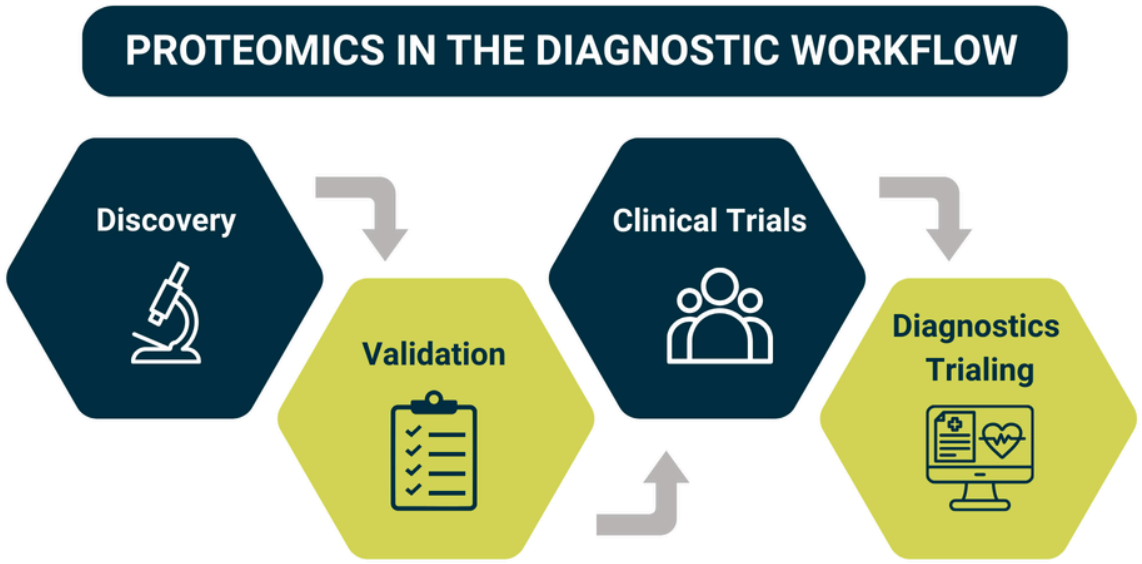


Figure 3. This flowchart illustrates the full translational pathway of proteomics, from biomarker discovery through validation, clinical trials, and nto diagnostic use and patient monitoring. Simoa technology acts as the bridge between discovery and clinical validation: enabling ultra-sensitive detection of novel targets from discovery studies, validating biomarkers across cohorts, powering pharmacodynamic endpoints in trials, and delivering clinically relevant results for early detection and disease tracking. Proteomics, once limited to research labs, is now a fully integrated component of the diagnostic development pipeline

Cross-sector collaboration will also be essential to continue this momentum. Academia, pharmaceutical innovators, and diagnostic developers each play a role in shaping the next era of proteomics, from identifying novel biomarkers to validating clinical use cases and navigating regulatory pathways. Quanterix's technology provides the common infrastructure to unite these stakeholders, fostering translational continuity and accelerating time to impact.

Proteomics is no longer aspirational. It is actionable. What was once confined to discovery laboratories is now embedded in regulatory submissions, diagnostic algorithms, and therapeutic development strategies. This transformation has not happened by accident; it has required technologies capable of keeping pace with biological complexity and clinical rigor alike. Simoa has risen to meet that challenge. From enabling the detection of trace biomarkers to establishing reproducibility across global clinical trials, Simoa has helped shape the evolution of proteomics from an experimental tool into a clinical force. The trajectory of modern biomedicine now bends through proteins, measured not just sensitively, but reliably, in a scalable manner, and meaningfully. Simoa's emergence marks not just a technical advancement but a structural shift in how proteomics informs clinical and translational science.

This whitepaper was written by Shana Tetrault, PhD, Director of Product Marketing, Quanterix

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