

WHITE PAPER

CIRCLES FOR THE EVIDENCE-BASED USE OF PEPTIDES

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EXECUTIVE SUMMARY

The global therapeutics landscape is undergoing a profound transformation, with peptides emerging as a dynamic and high-growth segment. Defined as short chains of amino acids, these molecules are gaining prominence for their versatility and targeted therapeutic action across a wide range of applications, from metabolic disorders to aesthetic medicine. As the market expands, it is projected to reach an estimated USD 84 billion by 2034, with North America currently leading and Asia Pacific positioned for the fastest growth. This market boom, however, presents a critical challenge: the data required to navigate its complexities and secure its future is largely unavailable through traditional methods.

The gold standard of drug development, the randomized controlled trial (RCT), is proving insufficient to capture the full scope of a peptide's real-world performance. RCTs often result in a limited, homogenous dataset, leaving significant gaps in understanding how peptides perform in diverse patient populations, with long-term use, or when combined with other therapies. This data deficit creates obstacles for regulatory approval, payer reimbursement, and the optimization of clinical practice.

A new paradigm is required to bridge this gap. Real-World Evidence (RWE), derived from the analysis of Real-World Data (RWD), offers a solution by providing a more complete, representative, and continuous view of patient outcomes. This paper posits that high quality, longitudinal RWE is not merely a supplement to traditional research but a strategic imperative. RegenMed's Circles are well positioned to collect this high-quality RWD in a cost- and clinically-efficient manner, thereby accelerating innovation, informing policy, and unlocking new commercial opportunities for all stakeholders in the peptide ecosystem.

THE PEPTIDES REVOLUTION

What are Peptides?

Peptides are fundamental biological molecules defined as short chains of amino acids linked together by peptide bonds. They are the building blocks of proteins, but they are significantly smaller in size, typically containing between two and fifty amino acids. This unique structure allows them to play a vital and diverse role in numerous physiological processes.

Acting as hormones, neurotransmitters, and signaling molecules, peptides regulate a wide array of bodily functions, from metabolism and appetite to immune response and nerve communication. Their ability to interact with specific receptors in a highly targeted manner is a key reason for their therapeutic potential and growing prominence as a class of treatment modalities.

Therapeutic Applications

The therapeutic applications of peptides are vast and continue to expand, reflecting a growing appreciation for their precision and efficacy. In the realm of anti-aging and aesthetics, peptides such as GHK-Cu and palmitoyl pentapeptide are utilized in skincare products to stimulate collagen production and improve skin elasticity, thereby reducing the appearance of wrinkles. In sports medicine and regenerative health, compounds like BPC-157 have been studied for their capacity to promote tissue repair, reduce inflammation, and accelerate recovery from injuries.

Perhaps the most significant commercial driver of the current market boom is the use of peptides for metabolic health and weight management. FDA-approved peptides like semaglutide and tirzepatide have demonstrated remarkable success in regulating appetite and improving metabolic function for individuals with type 2 diabetes and obesity. The success of these compounds has significantly increased public and professional interest in the field. Beyond these high-profile applications, peptides are also being explored for their ability to modulate the immune system, regulate hormones, and enhance neurological and cognitive function.

The wide array of applications, from clinical to wellness, indicates a fundamental shift in how the public and medical community view health. Peptides are increasingly seen as a targeted, often "natural," alternative to broad-spectrum drugs, aligning with the rise of personalized medicine and the longevity economy. This consumer demand, which often outpaces formal clinical evidence, is a key driver of the market boom and, paradoxically, a primary reason for the data deficit that this paper addresses.

Key Players and Market Drivers

The peptide therapeutics market is a rapidly growing field, attracting investment from a diverse group of stakeholders. Major pharmaceutical and biopharmaceutical companies such as Eli Lilly and Company, Amgen, Novo Nordisk, and Pfizer are all heavily invested,

with extensive research and development (R&D) pipelines and commercialized products. In addition, specialized peptide companies like Zealand Pharma and Contract Research and Manufacturing Organizations (CRO/CMOs) like Bachem and GenScript Biotech play a crucial role in developing and manufacturing these compounds for academic and commercial clients.

The primary drivers behind the recent surge in peptide popularity are multifold. The resounding commercial success of GLP-1 receptor agonists for weight loss and diabetes has created a massive commercial market and driven public interest. Furthermore, the rise of the wellness and anti-aging industries has created a strong consumer-driven demand for targeted, "natural" health solutions. Many peptides mimic the body's own signaling molecules, which gives them a non-invasive appeal that is particularly attractive to a modern consumer base.

[Appendix A](#) provides a deeper dive into the peptides therapeutics market.

CHALLENGES OF TRADITIONAL PEPTIDE RESEARCH

Despite the significant momentum and investment in the peptide space, the industry faces a fundamental challenge: a deficit of high-quality, comprehensive data. This issue stems from the limitations of traditional data collection methods and the unique characteristics of peptides themselves.

The Limitations of Randomized Controlled Trials

RCTs are the long-standing gold standard for proving a drug's efficacy and safety for regulatory approval. However, their highly controlled nature and strict inclusion and exclusion criteria often result in a patient population that is not representative of the diverse group of individuals who will eventually use the drug in the real world. This creates "data holes" and a significant lack of insight into how peptides perform in crucial patient demographics, including:

- Older patients and individuals with multiple comorbidities who are often excluded from trials due to the complexity of their health profiles.
- Different racial and ethnic groups, which can have varying responses to treatments due to genetic or environmental factors.

- Patients who are not perfectly adherent to the treatment regimen, reflecting the realities of daily life where perfect compliance is not always possible.

These narrow datasets make it difficult to extrapolate the results of RCTs to a broader, more heterogeneous population, limiting the generalizability of their findings.

The Problem of Data Fragmentation and Inconsistency

Traditional data collection methods in peptide drug discovery and development are often inconsistent and disorganized. The reliance on manual processes and fragmented tools, such as spreadsheets, leads to significant challenges. This can result in human error, poor data integrity, and a lack of interoperability, making it difficult to scale and analyze large datasets.

As the volume of peptide research and clinical use increases, these outdated methods are proving to be a major bottleneck, hindering the ability to draw meaningful conclusions and share information effectively across the industry.

Scarcity of Long-Term Outcome and Safety Data

Clinical trials are conducted over a finite period, which leaves significant gaps in our understanding of the long-term effects of a peptide drug. This is a particularly critical issue for peptides used in the treatment of chronic conditions, such as obesity and diabetes. Without long-term data, it is impossible to fully understand the durability of the treatment effect, identify rare or long-tail side effects that may only emerge after years of use, and assess the true impact on patient-reported outcomes over time.

Furthermore, it is essential to collect data on other adjunct therapies that patients are using while taking a peptide. The human body is a complex system, and a patient's health outcomes are rarely the result of a single intervention. Without collecting data on all relevant therapies, it is difficult to isolate causal relationships and assess potential synergistic or antagonistic effects, which can significantly alter a peptide's efficacy and safety profile.

HIGH QUALITY REAL-WORLD EVIDENCE FOR PEPTIDES

Defining RWE

To address the limitations of traditional research, the healthcare industry is increasingly turning to real-world evidence. High quality RWE – such as that contained within Circle Datasets -- is the longitudinal, verifiable and well-structured clinical evidence regarding the usage and potential benefits or risks of a medical product. RWE provides a window into how therapies are used and how they perform in the complex reality of clinical practice.

The Value Proposition of Circle Datasets

Circle Datasets represent strategic assets for the peptide ecosystem. They directly complement traditional clinical trials by providing a more comprehensive understanding of a drug's performance in a diverse, real-world patient population. The benefits of this approach are significant:

- **Broader Patient Insights:** Circle Datasets includes data from a much larger and more diverse patient population than is typically represented in clinical trials. This allows researchers to understand a peptide's real-world effectiveness, safety, and adherence in groups that may have been underrepresented in traditional studies.
- **Post-Market Surveillance and Safety:** Circles are a powerful tool for continuous post-market surveillance. They help identify rare adverse events or safety signals that might not have been detected in a smaller, controlled trial, thereby allowing for a more comprehensive and continuous safety profile of the drug.
- **Informing Regulatory and Payer Decisions:** Regulatory bodies like the FDA and payers such as insurance companies are increasingly using RWE to make decisions about drug approvals, new indications, and formulary placement. For peptides, Circle Datasets can provide a strong case for a drug's value by demonstrating its effectiveness and cost-benefit in routine clinical practice, which can help accelerate its adoption and patient access.

Key Stakeholders and the Data Economy

Circle Datasets can support the strategic goals of a wide range of organizations. These include:

- **Pharmaceutical and Biopharmaceutical Companies:** These companies use RWD to support regulatory submissions, understand market dynamics, optimize clinical trial design, and identify new therapeutic applications for their products.
- **Contract Research Organizations (CROs):** CROs leverage RWD to conduct observational studies, patient registries, and post-market surveillance for their life sciences clients.
- **Health Technology Assessment (HTA) Bodies and Payers:** Organizations like the National Institute for Health and Care Excellence (NICE) in the UK and private insurers use RWD to evaluate the cost-effectiveness and value of new therapies for reimbursement decisions.
- **Academic and Research Institutions:** Researchers use RWD to conduct large-scale epidemiological studies, analyze treatment patterns, and generate hypotheses for future research.

Moreover, the interest of payers and regulatory bodies in RWE signifies a fundamental shift in the healthcare ecosystem. These organizations are moving beyond pure efficacy data to demand evidence of *value*, which includes cost-effectiveness, long-term outcomes, and performance in routine clinical practice. This shift makes RWE not just a supplement but a commercial and regulatory necessity for any new peptide therapy seeking to achieve widespread adoption.

How Circles Address Key Data Challenges

The platform's patented physician-facing [inCytes™](#) and patient-facing [Benchmarc™](#) platforms – coupled with [processes](#) designed to minimize clinical burden -- allow clinicians accurately and efficiently to aggregate verifiable structured data on specific patient cohorts, pathologies, and treatment protocols. They directly address the data challenges identified in this report:

- **Solving Limited Patient Representation:** Circles enable the collection of data on a diverse range of patients who are typically underrepresented in clinical trials, such as older individuals or those with multiple comorbidities. By collecting data from real-world settings, they provide a more accurate picture of how peptides perform in different patient types and with various concomitant medications.
- **Addressing Lack of Long-Term Outcomes:** Circles capture well-correlated outcomes data over extended periods. Patients can use the Benchmarc™ app to complete surveys and review progress, reducing the burden on clinics and ensuring

consistent follow-up. This long-term data collection is crucial for understanding the durability of a peptide's effect and its long-term safety profile.

- **Generating High-Quality, Validatable Data:** As a closed system, Circles collect proprietary, clinically validated, auditable, and regulatorily compliant datasets. They are "FDA-fit for purpose," meeting the standards required for regulatory submissions. They can thus be used to support new drug indications or post-market surveillance. This provides a significant advantage over unstructured data sources like electronic health records (EHRs) alone.
- **Facilitating Collaboration and Addressing Fragmentation:** The platform enables clinicians to collaborate with peers wherever located, allowing them to share data and insights within and across institutional and national borders. This helps to overcome the issue of fragmented and siloed data. The ability to create custom, single-protocol studies allows for the collection of structured, standardized data; this is essential for consistent analysis and drawing meaningful conclusions.

Important Areas for Peptides Real-World Evidence

Clinical use of peptides requiring high quality RWE datasets include:

- **Metabolic Disorders (Obesity and Diabetes):** This is the most significant area for peptide therapeutics right now due to the immense popularity of GLP-1 receptor agonists like Ozempic and Wegovy. Data on long-term safety, sustained weight loss, and the management of side effects would be highly valuable to both researchers and pharmaceutical companies.
- **Anti-Aging and Aesthetics:** This is a vast and growing market driven by consumer demand. Data collection in this area could focus on patient-reported outcomes (PROs) regarding skin elasticity, wrinkle reduction, and overall appearance, which could be used to support marketing claims and inform treatment protocols.
- **Muscle Growth and Injury Recovery:** Peptides like BPC-157 are widely used in sports medicine and for general recovery. Collecting data on treatment efficacy for musculoskeletal injuries, as well as patient-reported measures of recovery time and pain, would provide valuable evidence for the use of these peptides.

Illustrative Circles Observational Protocols

Knee; BPC-157 for Ligament/Tendon Healing

Anatomical Region: Knee joint and periarticular structure.

- Pathology:** Partial medial collateral ligament (MCL) tear or patellar tendinopathy.
- Treatment Protocol:** BPC-157 (250–500 mcg daily). Subcutaneous injection adjacent to injury site for 4–6 weeks. Adjunct Therapies: Standard physiotherapy, cryotherapy as needed.
- Outcomes Assessment:** Follow-Up: Weekly in-clinic visits during treatment, then at 3, 6, and 12 months. MRI confirmation of injury at baseline and 3 months. Patient-reported pain and function (KOOS & VAS scales) at baseline, 6 weeks, 3 months, 6 months, 12 months. Return-to-sport/work timelines. Adverse events or concomitant therapies. Durability of ligament/tendon healing at 12 months. Reinjury incidence within 18 months. Patient satisfaction and activity levels (Tegner activity scale)

Obesity/Type 2 Diabetes; Semaglutide for Weight & Glycemic Control

- Anatomical Region:** Abdominal/metabolic system
- Pathology:** Obesity (BMI \geq 30) with or without type 2 diabetes
- Treatment Protocol:** Semaglutide (GLP-1 receptor agonist) per FDA label (titrated weekly injections up to 2.4 mg). **Lifestyle:** Standardized nutrition and activity counseling provided at baseline and reinforced monthly. **Follow-Up:** Monthly during first 6 months, then quarterly for up to 2 years.
- Outcomes Assessment:** Baseline weight, BMI, HbA1c, lipid panel, blood pressure. Weight, BMI, HbA1c every 3 months. Patient-reported quality of life (SF-36) and treatment adherence. Adverse events (GI effects, hypoglycemia) and concomitant medications. Sustained weight loss \geq 10% at 12 and 24 months. Maintenance of HbA1c reduction \geq 1.0% at 24 months. Cardiometabolic event incidence (e.g., hypertension, CV

events) over 2 years. Patient reported scores on energy, mobility, and satisfaction

Anti-Aging/Aesthetics; GHK-Cu for Dermal Remodeling

Anatomical Region:	Facial skin (periorbital and cheek regions)
Pathology:	Photoaging with fine lines and reduced skin elasticity
Treatment Protocol:	GHK-Cu serum or microneedling-assisted topical application (0.05% nightly) for 12 weeks. Adjunct: Standard SPF and skincare regimen standardized for participants
Outcomes Assessment:	Baseline, 6 weeks, 12 weeks, then 6, 12, and 18 months. High-resolution dermoscopic imaging at baseline, 12 weeks, and 12 months. Objective skin elasticity and wrinkle depth measurements (cutometer analysis). Patient-reported outcomes: FACE-Q scales for appearance satisfaction and social confidence. Adverse reactions (erythema, irritation). Maintenance of improved elasticity and wrinkle reduction at 12–18 months. Patient satisfaction scores over time. Documentation of any delayed adverse effects or pigment changes.

STRATEGIC RECOMMENDATIONS

The collection of real-world peptide data from patients and physicians closes the gap between controlled clinical trials and everyday medical practice. For all key players in the healthcare ecosystem, this data is a crucial asset that can inform strategy, accelerate innovation, and drive commercial success.

For Pharmaceutical and Biotech

Major pharmaceutical and biotech companies can leverage Circle Datasets to gain competitive advantage. The strategic recommendations shift the value proposition of a peptide from a simple drug to an entire evidence-based solution. The company is no longer just selling a molecule; it is offering a continuous feedback loop of real-world data that

supports its product, enhances physician education, and strengthens its relationship with regulators and payers.

- **Generate Evidence for New Indications:** Companies can sponsor Circles focused on specific off-label uses to collect structured RWE. This provides a rich dataset that can be used to support a formal application for expanded use or inform future clinical trial design.
- **Demonstrate Long-Term Value to Payers:** By funding Circles-based programs focused on an approved drug, companies can collect data on sustained outcomes (e.g., sustained weight loss, cardiovascular risk reduction). This provides powerful evidence to strengthen marketing claims and secure better reimbursement from insurance providers.
- **Optimize Treatment Protocols and Enhance Physician Education:** A company could fund a Circle where expert clinicians collectively refine and standardize a treatment protocol. The resulting data and protocols could be licensed to a broader network of physicians, ensuring a higher standard of care and building brand loyalty.
- **Capture Patient-Reported Outcomes:** Circles Datasets can be designed to capture data on patient well-being, satisfaction, and the impact of the therapy on their daily lives, which is a crucial metric for regulatory bodies and for proving a drug's value.

For Clinicians and Researchers

Clinicians and researchers can generate clinically and statistically significant Circle Datasets representing a robust evidence base for off-label peptide use. Through their expertise and data, they can refine treatment protocols and position themselves as thought leaders in a rapidly evolving field. Circles empower physician-investigators to own and monetize their data, providing a new revenue stream and a way to capitalize on their clinical expertise.

For the Broader Ecosystem

The benefits of a data-centric approach extend to all stakeholders in the healthcare ecosystem. Patients benefit from more effective and personalized treatment as their physicians can access a broader, more accurate evidence base. For researchers, this approach provides a wealth of information to accelerate the pace of scientific discovery and inform new studies. For the industry as a whole, it provides a crucial, agile, and cost-effective way to navigate a complex regulatory environment and demonstrate the full value of new therapeutic peptides.

CONCLUSION

The peptide therapeutics market stands at a critical juncture. The scientific breakthroughs and market momentum are undeniable, but their full potential cannot be realized with the data collection methods of the past. The limitations of traditional randomized controlled trials, coupled with the fragmentation and inconsistency of unstructured data, create a fundamental barrier to growth. The evidence presented in this report indicates that RWE is not just an alternative to traditional data collection but a superior, more holistic, and scalable model for the future of peptide innovation.

Circles are a powerful tool in this new paradigm. By generating structured, auditable, and regulatory-compliant RWE from routine clinical practice, they bridge the critical gap between a wealth of anecdotal evidence and a lack of formal, scientifically rigorous research. They provide a continuous and dynamic feedback loop that informs clinical decisions, accelerates regulatory processes, and empowers all stakeholders.

The strategic adoption of such a data-centric approach will be the defining factor for any company, clinician, or researcher seeking to lead and thrive in this burgeoning market, ultimately benefiting patients through more effective and personalized care.

APPENDIX A: THE PEPTIDES THERAPEUTICS MARKET

Market Valuation and Growth Drivers

The global peptide therapeutics market is on a significant upward trajectory. According to a market analysis, the global market size was estimated at USD 49 billion in 2024 and is projected to increase from USD 53 billion in 2025 to approximately USD 84 billion by 2034.

A Regional and Segment Breakdown

Globally, the market is geographically segmented, with North America currently holding the largest share. In 2024, the North American market accounted for 46% of the global market, reaching a valuation of USD 23 billion. This dominance is largely attributable to a well-established biotechnology and pharmaceutical industry, significant R&D funding, and a high consumer demand for advanced therapies.

While North America is the market leader, the Asia Pacific region is projected to be the fastest-growing market for peptide therapeutics, with a forecasted CAGR of 6% between 2025 and 2034. This rapid expansion is driven by a rising burden of chronic diseases, expanding healthcare infrastructure in countries like China and India, and the ability to produce peptides at a lower cost.

By application, the metabolic disorder segment has emerged as the most dominant, capturing approximately 23% of the market share in 2024. The gastrointestinal disorder segment is also poised for significant growth, with a projected CAGR of 6%. The parenteral route of administration, primarily injections, remains the most common, accounting for over 76% of revenue share in 2024, though the oral segment is expanding at a CAGR of 6%.

The Future of Peptide Development and Spending

The future of peptide development is characterized by a confluence of scientific and technological innovations aimed at improving synthesis, efficiency, and cost-effectiveness. Future advancements in peptide synthesis will focus on high-throughput synthesis, automation, and the use of artificial intelligence (AI) and computational design to predict peptide structures and optimize synthesis pathways. These innovations will accelerate drug discovery, shorten development cycles, and reduce costs.

New manufacturing processes, such as the μ LOT technology, are also poised to drive significant momentum by enabling true continuous manufacturing of peptides, which can replace traditional, expensive batch processes. This will not only reduce cycle times and labor costs but also address the significant environmental impact of the industry, which is currently estimated to have toxic waste disposal costs of between USD 1 billion and USD 1.5 billion based on 2025 sales.

The high cost of toxic waste disposal in traditional synthesis further incentivizes the adoption of new, cleaner technologies, which will, in turn, accelerate the pipeline of peptides requiring real-world validation. This confluence of market growth, driven by demand, and manufacturing innovations, which improve supply and cost-effectiveness, creates a powerful feedback loop. As it becomes cheaper and faster to produce a wider variety of peptides, the need for a scalable and efficient way to collect real-world data on their use becomes paramount to secure regulatory approval and widespread market adoption.

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