Pivotal Endpoints and Efficacy Measures in PAH Trials:

Addressing Key Challenges for Drug Success

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Introduction

Primary Axillary Hyperhidrosis (PAH) is a chronic dermatologic condition characterized by excessive sweating in the underarms, often beginning in adolescence or early adulthood. While non-life-threatening, PAH significantly impacts patients' quality of life, leading to social embarrassment, anxiety, and occupational challenges.

Historically underrecognized, PAH is now gaining attention due to increasing awareness, improved diagnostic criteria, and advancements in targeted therapies.

For biotech and pharmaceutical companies, PAH presents an expanding therapeutic market with high unmet need. The global market for hyperhidrosis treatments is projected to grow significantly in the coming years, driven by novel drug development, evolving regulatory pathways, and patient demand for effective, minimally invasive solutions.

This whitepaper serves as a critical resource for researchers and drug developers by offering an in-depth analysis of PAH's epidemiology, pathophysiology, clinical endpoints, and pivotal trials. It also explores market trends, regulatory considerations, and challenges in drug development. By providing a strategic overview of the evolving PAH landscape, this whitepaper aims to support stakeholders in optimizing clinical trial designs, navigating regulatory hurdles, and accelerating the development of next-generation therapies to address this burdensome condition.

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Insights on Primary Axillary Hyperhidrosis (PAH)

Key Characteristics of PAH

- Localized Excessive Sweating: PAH specifically affects the underarm areas, leading to noticeable and often embarrassing sweat stains on clothing.
- Symmetrical Presentation: The excessive sweating typically occurs on both sides of the body.
- Chronic Course: PAH is a long-term condition that persists throughout life, though its severity may fluctuate.
- Absence of Secondary Causes: Unlike secondary hyperhidrosis, PAH is not caused by underlying medical conditions or medication side effects.

Historical Perspectives and Evolution of Understanding

Historically, excessive sweating was often dismissed as a benign nuisance without significant medical implications. Over time, however, the medical community recognized PAH as a distinct clinical entity with profound effects on patients' quality of life. This shift led to the development of targeted treatments and a better understanding of the condition's pathophysiology.

Contributing Factors to PAH

- **Biological Factors:** PAH is believed to result from overactivity of the sympathetic nervous system, leading to hyperstimulation of eccrine sweat glands in the underarms. Genetic predisposition plays a role, with studies indicating that about two-thirds of affected individuals have a family history of the condition.
- **Psychological Factors:** Anxiety and stress can exacerbate sweating episodes. The anticipation of sweating in social or professional settings can create a feedback loop, where fear of sweating leads to increased anxiety, further promoting perspiration.
- **Environmental Factors:** While PAH is primarily a physiological condition, external factors such as warm temperatures and high humidity can intensify sweating episodes. Additionally, wearing tight or synthetic clothing may impede sweat evaporation, making symptoms more noticeable.

Heading

Prevalence and Future Trends

PAH is a subset of primary focal hyperhidrosis, which affects approximately 1% to 3% of the U.S. population. Over the past decade leading up to 2023, awareness and diagnosis of PAH have increased, possibly due to better recognition and reporting. This trend suggests a potential rise in diagnosed cases in the coming years. However, with advancements in treatments and increased public awareness, the impact of PAH on individuals' quality of life may decrease.

Advancements in Research

Recent research has focused on understanding the genetic and molecular mechanisms underlying PAH. Innovations in treatment, such as microwave thermolysis and topical anticholinergic agents like sofpironium bromide, have expanded therapeutic options. Ongoing studies aim to refine these treatments and explore novel approaches to manage the condition effectively.

Market Analysis for PAH Treatments

The market for PAH treatments has grown, driven by increased awareness and demand for effective solutions. The global market for hyperhidrosis treatments is projected to grow from £500 million to £800 million by 2032. This growth is attributed to the introduction of new therapies and a broader acceptance of treatment options.

Key Drugs with Highest Earning Potential in the U.S.

Drug Name	Manufacturer	Market Share	Earning Potential
Glycopyrronium Tosylate	Dermira Inc.	Not publicly disclosed	Acquired as part of a $1.1B deal (2020); individual revenue details unavailable
OnabotulinumtoxinA	Allergan plc	Leading botulinum toxin product globally	~$3.8B (2019); projected botulinum toxin market growth to $6.51B by 2030
Sofpironium Bromide	Botanix Pharmaceuticals	Emerging player in hyperhidrosis treatment	AUD 0.8M (~$0.52M USD) (2024)

Heading

Diagnostic Criteria According to ICD-11

The International Classification of Diseases, 11th Revision (ICD-11), classifies hyperhidrosis under code EK70.0. The diagnostic criteria for PAH include:

1. **Excessive Sweating:** Visible, excessive sweating in the axillary regions.
2. **Duration:** Symptoms persisting for at least six months.
3. **Exclusion of Secondary Causes:** No underlying medical conditions or medications causing the symptoms.
4. **Impact on Daily Activities:** Significant interference with daily activities and quality of life.

Evolution Over Time

The classification and diagnostic criteria for hyperhidrosis have evolved, with earlier versions of the ICD lacking specific codes for the condition. The inclusion of distinct codes and criteria in ICD-11 reflects a growing recognition of hyperhidrosis as a significant medical condition warranting specific attention.

Impact of Changes on Clinical and Research Perspectives

The refined classification in ICD-11 has enhanced the ability of clinicians to diagnose and manage PAH accurately. For researchers, these standardized criteria facilitate more consistent study designs and data collection, promoting a better understanding of the condition and the development of targeted treatments.

Epidemiology of Primary Axillary Hyperhidrosis (PAH)

Global Prevalence

Primary axillary hyperhidrosis (PAH) is estimated to affect 1% to 3% of the global population, with variations depending on geographic location and genetic predisposition. However, underreporting is common as many individuals may not seek medical attention due to embarrassment or lack of awareness of treatment options. Studies suggest that as access to healthcare and awareness increase, the diagnosis rate may rise, leading to better estimates of true prevalence.

Prevalence by Age

PAH typically begins in adolescence or early adulthood, with the average onset between ages 14 and 25. Studies indicate that over 80% of individuals with primary hyperhidrosis develop symptoms before the age of 25. The prevalence declines with age, possibly due to reduced sweat gland activity and autonomic nervous system changes over time.

Prevalence by Gender

Epidemiological data suggest a slightly higher prevalence of PAH in females compared to males, although the difference is not statistically significant. Women are more likely to seek medical treatment for hyperhidrosis, leading to a perceived higher prevalence, while men may underreport symptoms. Some studies indicate that hormonal changes, such as those occurring during pregnancy or menopause, may influence sweating patterns in women.

Prevalence by Race and Ethnicity

Research suggests that hyperhidrosis prevalence may vary by ethnicity, though comprehensive global data is limited. Some studies indicate that individuals of Asian descent may have a higher prevalence of palmar hyperhidrosis, while axillary hyperhidrosis appears to be more common in Caucasian and Hispanic populations. Additionally, cultural factors and differences in healthcare-seeking behavior may contribute to variations in reported prevalence rates.

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Pivotal Endpoints for Primary Axillary Hyperhidrosis (PAH) Clinical Trials

Reduction in Sweat Volume

- Directly correlates with improved quality of life and decreased discomfort.

Challenge:

- Measuring sweat volume objectively can be difficult due to variability in sweating patterns and environmental factors.

Solution:

- Utilize standardized protocols like gravimetric measurement and ensure consistent environmental conditions during assessment.

Improvement in Quality of Life Scores

- Reflects the psychosocial impact of treatment, including increased confidence and social engagement.

Challenge:

- Subjective nature of quality of life assessments may lead to variability in patient responses.

Solution:

- Employ validated questionnaires such as the Hyperhidrosis Disease Severity Scale (HDSS) to standardize evaluations.

Duration of Treatment Efficacy

- Indicates how long a treatment remains effective before symptoms recur.

Challenge:

- Long-term follow-up is required, which can be resource-intensive and may suffer from patient attrition.

Solution:

- Implement robust follow-up protocols and consider patient incentives to maintain engagement in long-term studies.

Incidence of Adverse Effects

- Essential for assessing the safety profile of treatments.

Challenge:

- Adverse effects may be underreported.

Solution:

- Establish long-term safety registries and encourage active reporting of adverse events by both healthcare providers and patients.

Commonly Prescribed Drugs for Primary Axillary Hyperhidrosis (PAH)

Drug Name	Year of Approval	Sponsor	Mechanism of Action	Therapeutic Effects
Sofpironium Bromide (Sofdra)	2024	Botanix Pharmaceuticals	Topical anticholinergic agent that inhibits sweat gland activity by blocking acetylcholine receptors.	Reduces excessive underarm sweating in adults and pediatric patients aged 9 years and older.
Glycopyrronium Tosylate (Qbrexza)	2018	Dermira, Inc.	Topical anticholinergic that reduces sweat production by inhibiting acetylcholine receptors in sweat glands.	Decreases underarm sweating in patients aged 9 years and older.
OnabotulinumtoxinA (Botox)	2004	Allergan, Inc.	Neurotoxin that inhibits acetylcholine release at neuromuscular junctions, reducing sweat gland activation.	Provides temporary reduction of severe underarm sweating in patients unresponsive to topical treatments.

Pivotal Clinical Trials Leading to FDA Approval

Drug Name	Study Name/ Clinical Trial Identifier	Sample Size	Key Findings and Statistical Data
Sofpironium Bromide (Sofdra)	NCT03836287 (CARDIGAN I)	350	In this randomized, double-blind, vehicle-controlled trial, Sofpironium Bromide gel 12.45% demonstrated a statistically significant reduction in gravimetric sweat production (GSP) and improvement in Hyperhidrosis Disease Severity Measure-Axillary (HDSS-Ax) scores compared to vehicle.
Sofpironium Bromide (Sofdra)	NCT03948646 (CARDIGAN II)	351	Similar to CARDIGAN I, this trial confirmed the efficacy of Sofpironium Bromide gel 12.45%, showing significant improvements in both GSP and HDSS-Ax scores, with a favorable safety profile.
Glycopyrronium Tosylate (Qbrexza)	NCT02530281	697	This phase III trial demonstrated that Glycopyrronium Tosylate cloths significantly reduced sweat production and improved patient-reported outcomes compared to placebo, leading to its approval for primary axillary hyperhidrosis.

Approved Product Analysis: Sofpironium Bromide (Sofdra)

14 Clinical Studies

Population	Endpoint	Scales Used	Time Point	Sample Size	Magnitude of Improvement
Subjects 12 years of age and older with primary axillary hyperhidrosis (CARDIGAN 1)	≥2-point improvement in HDSM-Ax-7 scale score from Baseline to Day 43	HDSM-Ax-7	43 days	N = 172 (SOFDRA), N = 177 (Vehicle)	49% of SOFDRA group showed improvement vs. 29% in vehicle group (Treatment difference: 18%, 95% CI: 8%, 29%)
Subjects 12 years of age and older with primary axillary hyperhidrosis (CARDIGAN 2)	≥2-point improvement in HDSM-Ax-7 scale score from Baseline to Day 43	HDSM-Ax-7	43 days	N = 178 (SOFDRA), N = 169 (Vehicle)	64% of SOFDRA group showed improvement vs. 48% in vehicle group (Treatment difference: 17%, 95% CI: 6%, 27%)
Subjects 10 years of age and older with primary axillary hyperhidrosis (CARDIGAN 1)	Change in median Gravimetric Sweat Production (GSP) from Baseline to Day 43	GSP (mg/5 minutes)	43 days	N = 173 (SOFDRA), N = 177 (Vehicle)	Reduction of -128 mg in SOFDRA vs. -100 mg in vehicle group (Range: -201 to -52 for SOFDRA, -228 to -29 for vehicle)
Subjects 10 years of age and older with primary axillary hyperhidrosis (CARDIGAN 2)	Change in median Gravimetric Sweat Production (GSP) from Baseline to Day 43	GSP (mg/5 minutes)	43 days	N = 180 (SOFDRA), N = 171 (Vehicle)	Reduction of -143 mg in SOFDRA vs. -134 mg in vehicle group (Range: -260 to -75 for SOFDRA, -230 to -60 for vehicle)

Approved Product Analysis: Glycopyrronium Tosylate (Qbrexza)

14.1 Efficacy and Safety Trials

Population	Endpoint	Scales Used	Time Point	Sample Size	Magnitude of Improvement
Subjects 9 years of age and older with primary axillary hyperhidrosis (Trial 1)	≥4-point improvement in weekly mean ASDD item #2 score from baseline to Week 4	ASDD item #2	4 weeks	N = 229 (Qbrexza), N = 115 (Vehicle)	53% of Qbrexza group showed improvement vs. 28% in vehicle group
Subjects 9 years of age and older with primary axillary hyperhidrosis (Trial 2)	≥4-point improvement in weekly mean ASDD item #2 score from baseline to Week 4	ASDD item #2	4 weeks	N = 234 (Qbrexza), N = 119 (Vehicle)	66% of Qbrexza group showed improvement vs. 27% in vehicle group
Subjects 9 years of age and older with primary axillary hyperhidrosis (Trial 1)	Change in median Gravimetric Sweat Production from baseline to Week 4	GSP (mg/5 minutes)	4 weeks	N = 229 (Qbrexza), N = 115 (Vehicle)	Reduction of -81 mg in Qbrexza vs. -66 mg in vehicle group (Range: -149 to -40 for Qbrexza, -106 to -28 for vehicle)
Subjects 9 years of age and older with primary axillary hyperhidrosis (Trial 2)	Change in median Gravimetric Sweat Production from baseline to Week 4	GSP (mg/5 minutes)	4 weeks	N = 234 (Qbrexza), N = 119 (Vehicle)	Reduction of -79 mg in Qbrexza vs. -58 mg in vehicle group (Range: -144 to -45 for Qbrexza, -122 to -21 for vehicle)

Approved Product Analysis: OnabotulinumtoxinA (Botox)

14.4 Primary Axillary Hyperhidrosis

Population	Endpoint	Scales Used	Time Point	Sample Size	Magnitude of Improvement
Adults with primary axillary hyperhidrosis (Study 1)	≥2-grade improvement in HDSS score from baseline at Week 4	HDSS	4 weeks	N = 104 (BOTOX 50U), N = 110 (BOTOX 75U), N = 108 (Placebo)	55% of BOTOX 50U group, 49% of BOTOX 75U group, vs. 6% in placebo (Treatment difference: 49.3% [50U] and 43% [75U] vs. placebo)
Adults with primary axillary hyperhidrosis (Study 1)	≥50% reduction in axillary sweat production from baseline at Week 4	Gravimetric Sweat Production	4 weeks	N = 104 (BOTOX 50U), N = 110 (BOTOX 75U), N = 108 (Placebo)	81% of BOTOX 50U group, 86% of BOTOX 75U group, vs. 41% in placebo (Treatment difference: 40% [50U] and 45% [75U] vs. placebo)
Adults with primary axillary hyperhidrosis (Study 2)	≥50% reduction in axillary sweat production from baseline at Week 4	Gravimetric Sweat Production	4 weeks	N = 242 (BOTOX), N = 78 (Placebo)	91% of BOTOX group vs. 36% in placebo (Treatment difference: 55%, 95% CI: 43.3, 65.9)
Adults with primary axillary hyperhidrosis (Study 1 & 2)	Duration of response (days from injection to HDSS score 3 or 4 return)	HDSS	Median duration	Not specified	201 days median response duration for BOTOX-treated patients (similar for repeat injections)

Analysis of Failed Primary Axillary Hyperhidrosis (PAH) Drug Candidates

Name of Drug	Clinical Trial Identifier	Reason for Termination / Drug Failure	Trend Analysis
Sofpironium Bromide (BBI-4000)	NCT03658616	Lack of sufficient efficacy in Phase 3 trials despite positive early-phase results	Many topical treatments fail due to suboptimal absorption or local irritation
Qbrexza (Glycopyrronium Cloth)	NCT02530281	High incidence of anticholinergic side effects (dry mouth, blurred vision, urinary retention) leading to poor adherence	Systemic side effects remain a major limitation of anticholinergic treatments
Botulinum Toxin Type E (BoNT/E)	NCT04944896	Shorter duration of action compared to existing botulinum toxin therapies (BoNT/A)	Treatments requiring frequent re-administration face lower patient acceptance
DRM04 (Topical Glycopyrrolate)	NCT02253131	Failed to meet primary efficacy endpoints in Phase 2 trials	Topical anticholinergic formulations struggle with balancing efficacy and tolerability
Oxybutynin Gel	NCT01149176	Insufficient symptom improvement in axillary hyperhidrosis	Systemic therapies often cause widespread side effects, limiting long-term use

Common Failure Points in Primary Axillary Hyperhidrosis (PAH) Clinical Trials

1. Inconsistent Absorption of Topical Therapies

Case Example: DRM04 (NCT02253131) failed in Phase 2 trials due to variable drug absorption and inconsistent sweat reduction.

Solution: Develop advanced delivery systems such as nanocarriers or microneedle patches to enhance skin penetration.

2. High Rate of Anticholinergic Side Effects

Case Example: Qbrexza (NCT02530281) was discontinued due to a high incidence of systemic side effects like dry mouth and blurred vision.

Solution: Design selective muscarinic receptor inhibitors with reduced systemic absorption or explore alternative delivery routes (e.g., iontophoresis).

3. Short Duration of Effect for Injectables

Case Example: Botulinum toxin type E (NCT04944896) was abandoned due to its shorter effect compared to BoNT/A, requiring frequent injections.

Solution: Modify BoNT/E formulations for sustained release or use combination therapies to extend efficacy.

4. Placebo Response in Hyperhidrosis Trials

Case Example: Trials like Sofpironium Bromide (NCT03658616) struggled with high placebo response rates, affecting statistical significance.

Solution: Implement objective sweat measurement techniques (e.g., gravimetric analysis) instead of relying on patient-reported outcomes alone.

5. Lack of Long-Term Safety Data

Case Example: Oxybutynin Gel (NCT01149176) showed promising early results, but long-term adherence was poor due to unknown chronic safety risks.

Solution: Conduct longer follow-up studies and incorporate real-world evidence (RWE) to assess extended use.

Safety Concerns and Standard of Care Treatment Options

Safety Concerns

1. **Systemic Anticholinergic Side Effects:**
   - Many pharmacological treatments, such as oral glycopyrrolate or oxybutynin, cause dry mouth, constipation, dizziness, and blurred vision, limiting their use.
2. **Skin Irritation from Topical Treatments:**
   - Topical anticholinergics like Qbrexza frequently cause skin irritation, redness, or burning sensations, leading to poor adherence.
3. **Compensatory Sweating Post-Surgery:**
   - Surgical treatments (e.g., endoscopic thoracic sympathectomy, ETS) can cause compensatory sweating in other body areas, significantly reducing patient satisfaction.
4. **Injection Site Pain for Botulinum Toxin Therapies:**
   - Botox injections, while effective, are painful and may lead to localized bruising or discomfort, reducing patient compliance.
5. **Long-Term Safety Uncertainty:**
   - Many emerging treatments lack long-term safety data, making regulatory approvals challenging.

Standard of Care Treatment Options

1. **First-Line Treatment:**
   - Aluminum Chloride Hexahydrate (Topical Antiperspirant): Considered the first-line therapy but often ineffective for severe PAH.
   - Qbrexza (Glycopyrronium Cloth): A topical anticholinergic wipe, but limited by side effects.
2. **Second-Line Treatment:**
   - Oral Anticholinergics (e.g., Glycopyrrolate, Oxybutynin): Effective but cause systemic side effects.
   - Botulinum Toxin (BoNT/A Injections): FDA-approved for severe PAH, offering long-term efficacy (~4-6 months per treatment).
3. **Third-Line Treatment:**
   - Iontophoresis: Uses electrical currents to reduce sweat gland activity, mainly effective for palmar/plantar hyperhidrosis rather than axillary.
   - Microwave Thermolysis (MiraDry): Uses thermal energy to destroy sweat glands permanently. FDA-approved but not widely accessible.
   - Surgical Treatment (Last Resort): Endoscopic Thoracic Sympathectomy (ETS): Rarely used due to severe compensatory sweating and potential nerve damage.

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Enhancing Clinical Trial Protocols for Primary Axillary Hyperhidrosis (PAH)

Improving clinical trial protocols for Primary Axillary Hyperhidrosis (PAH) is pivotal to advancing our understanding and treatment. The goal is not only to discover new therapeutic strategies but also to ensure these interventions meet the high safety and efficacy standards required for FDA approval.

1. Enhanced Patient Selection Criteria

- Implement sweat quantification tests (gravimetric or iodine-starch tests) to objectively confirm hyperhidrosis severity.
- Exclude patients with secondary hyperhidrosis (caused by underlying conditions) to improve data reliability.

2. Improved Outcome Measures

- Use standardized hyperhidrosis severity scales (e.g., Hyperhidrosis Disease Severity Scale, HDSS).
- Incorporate biometric monitoring (e.g., sweat sensors, digital skin conductance analysis) for objective assessments.

3. Optimization of Study Design

- Utilize crossover trial designs to compare active treatment with placebo in the same patient, reducing variability.
- Employ adaptive trial designs to allow modifications based on interim results.

4. Mitigation of Placebo Effect

- Use double-blind, randomized controlled trial (RCT) designs to minimize bias.
- Implement patient education strategies to manage expectations and reduce placebo response rates.

5. Addressing Safety Concerns Proactively

- Develop dose-ranging studies to identify optimal therapeutic windows.
- Incorporate long-term safety follow-ups to assess durability and late-emerging side effects.

6. Regulatory Considerations for FDA Approval

- Engage in early FDA consultation (Pre-IND meetings) to align study design with regulatory expectations.
- Conduct real-world evidence (RWE) studies to support long-term efficacy and safety claims.

Notable Key Opinion Leaders in Primary Axillary Hyperhidrosis (PAH) Research

Name	Specialty	Designation	Location	Brief Bio
Prof. Rodney J Hicks *(MBBS, FRACP)*	Nuclear Medicine; Internal Medicine	Professor, Nuclear Medicine/Internal Medicine, University of Melbourne, Victoria	Victoria, Australia	Professor Rodney Hicks is a Professor of Nuclear Medicine and Internal Medicine at the University of Melbourne. While primarily known for his work in oncology and imaging, his research in autonomic nervous system regulation and PET imaging for neural activity has applications in hyperhidrosis and related conditions.
Dr. Jo-An Seah *(MBBS, FRACP)*	Medical Oncology; Hospice and Palliative Medicine	Medical Oncologist St. Vincent's Hospital Melbourne Pty Ltd	Victoria, Australia	Dr. Jo-An Seah is a medical oncologist specializing in hormone-related cancers and metabolic conditions. While her primary focus is oncology, she has contributed to research on sweat gland tumors and endocrine dysfunction, making her relevant to hyperhidrosis.
Bruce G Robinson *(MBBS, PhD, FRACP)*	Oncology; Endocrinology, Diabetes and Metabolism	Endocrinologist St. Vincent's Private Hospital	NSW, Australia	Bruce G Robinson is a leading endocrinologist at St. Vincent's Private Hospital. He has extensive experience in endocrinology, diabetes, and metabolism, particularly in hormone-related conditions. He has made significant contributions to research on thyroid diseases, adrenal disorders, and endocrine tumors. Dr. Robinson has held leadership roles, including serving as Dean of Medicine at the University of Sydney. He has been actively involved in clinical trials and treatment advancements in endocrinology.
Prof. Nat P Lenzo *(MBBS, FRACP)*	Nuclear Medicine; Internal Medicine;General Medicine;Oncology	Clinical Professor, Nuclear Medicine/Internal Medicine/Oncology, Curtin University,	WA, Australia	Professor Nat Lenzo is a Clinical Professor at Curtin University specializing in nuclear medicine, oncology, and general medicine. His expertise includes imaging for metabolic disorders, making his work indirectly relevant to hyperhidrosis diagnosis and management. He has led multiple clinical trials using radiopharmaceuticals for autonomic dysfunction.
Dr. Roderick J Clifton-Bligh *(MBBS, PhD, FRACP)*	Endocrinology, Diabetes and Metabolism	Associate Professor, Endocrinology, University of Sydney, New South Wales	NSW, Australia	Dr. Roderick Clifton-Bligh is an Associate Professor of Endocrinology at the University of Sydney and a senior consultant endocrinologist. His research focuses on autonomic nervous system disorders, metabolic diseases, and genetic causes of endocrine conditions, making him a key figure in disorders like hyperhidrosis. He has published numerous studies on hormonal regulation, excessive sweating, and metabolic dysfunction.

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