



Understanding Attention-Deficit/Hyperactivity Disorder (ADHD): Epidemiology, Clinical Implications & Strategies for Clinical Trial Success

Introduction

Attention-Deficit/Hyperactivity Disorder (ADHD) is a neurodevelopmental disorder characterized by persistent patterns of inattention, hyperactivity, and impulsivity that are more frequent and severe than typically observed in individuals at a comparable level of development.

The understanding of ADHD has evolved significantly over time. Initially regarded as a behavioral problem primarily in children, ADHD was referred to as "Minimal Brain Dysfunction" in the early 20th century. It wasn't until the late 20th century that ADHD began to be recognized as a distinct psychiatric disorder that could also affect adults.

The evolving understanding of ADHD has significantly impacted clinical practice and research directions. Clinicians now adopt a more integrated approach in diagnosis and treatment, considering the individual's life context, comorbid conditions, and unique symptom presentation. In research, there is an increasing focus on identifying endophenotypes, exploring non-pharmacological interventions, and understanding the long-term outcomes of those living with ADHD.

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Key Characteristics and an Evolving Understanding

Key Characteristics

- **Predominantly Inattentive Presentation (ADHD-PI):**

Individuals with this subtype struggle primarily with inattention and distractibility without the hyperactive and impulsive behaviors seen in other types. Symptoms may include difficulty sustaining attention, following detailed instructions, organizing tasks, and a tendency to lose things.

- **Predominantly Hyperactive-Impulsive Presentation (ADHD-PH):**

This subgroup is characterized by hyperactivity and impulsiveness without significant inattention. Symptoms include fidgeting, talking excessively, difficulty waiting their turn, and impulsive behavior.

- **Combined Presentation (ADHD-C):**

This is the most common subtype and involves a mix of inattentive and hyperactive-impulsive symptoms. Individuals with this presentation display six or more symptoms of inattention and six or more symptoms of hyperactivity-impulsivity.

Historical Perspectives

The evolution in understanding has shifted the focus from merely controlling "problematic" behavior to a more comprehensive approach that considers biological underpinnings and environmental impacts.

- **Biological Factors:**

Research indicates that genetics play a crucial role in the development of ADHD. Family and twin studies have revealed a strong hereditary component, with multiple genes involved, each contributing a small effect size.

- **Psychological Factors:**

Psychological factors, including cognitive impairments and emotional dysregulation, are prevalent in individuals with ADHD. These can manifest as difficulties in executive functions such as planning, working memory, and inhibition control.

- **Environmental Factors:**

Environmental influences, such as prenatal exposure to toxins, early childhood experiences, and educational settings, play a significant role in the manifestation and severity of ADHD symptoms.

Diagnostic Evolution and Criteria

ICD-11 Criteria for ADHD

The ICD-11 categorizes ADHD under disorders of inattention, activity, and impulsivity. The code for this disorder is 6A05. To meet the diagnosis, there must be evidence of early onset, before the age of 12 years.

The degree of inattention and hyperactivity-impulsivity is outside the limits of normal variation expected for age and level of intellectual functioning. The ICD-11 emphasizes the necessity of cross-situationality — the presence of symptoms in multiple settings such as at home and in school or work environments.

For a diagnosis, these behaviors should be clear impairments in personal, social, educational, or occupational functioning and are not better accounted for by another mental, behavioural, or neurodevelopmental disorder and are not due to the effect of a substance or medication.

Evolution of Diagnostic Criteria

The diagnostic criteria for ADHD have evolved considerably. Earlier editions of the DSM did not fully recognize ADHD in adults, nor did they accommodate the varying ways symptoms can present across different age groups. With each revision, there has been a greater understanding and acknowledgment of the condition's complexity and its impact across the lifespan. This evolution reflects growing research and clinical awareness of ADHD's nature, leading to more comprehensive and inclusive criteria.

Impact on Clinical and Research Perspectives:

The changes in diagnostic criteria over time have significantly influenced clinical practices and research strategies. Clinicians are now equipped with a more nuanced understanding of ADHD, allowing for more accurate diagnosis and tailored treatment plans. For researchers, the refined criteria facilitate more precise study designs and participant selection, improving the quality and applicability of research findings. The evolution of diagnostic standards underscores the importance of continual research and adaptation in the face of emerging evidence.

Epidemiology of ADHD

Prevalence Rates

ADHD is one of the most common neurodevelopmental disorders in children, with studies indicating a global prevalence rate of approximately 5–7% among children and adolescents.

However, prevalence rates vary significantly depending on the diagnostic criteria used, the population studied, and the methodological approaches of the research. In adults, the prevalence is estimated to be around 2.5–5%, reflecting the disorder's persistence beyond childhood for many individuals.

Demographic Variances

- **Age:** ADHD is most commonly diagnosed in school-aged children, with symptoms often persisting into adolescence and adulthood
- **Gender:** Males are more frequently diagnosed with ADHD compared to females, with a ratio of approximately 2:1 in children and 1.6:1 in adults.
- **Geographical and Cultural Differences:** Variations in ADHD prevalence rates across different countries and cultures are likely influenced by diagnostic practices, awareness, and sociocultural attitudes towards the disorder.

Associated Risk Factors

- **Genetic Factors:** ADHD has a strong hereditary component, with genetics accounting for approximately 70–80% of the risk. Family, twin, and adoption studies have all highlighted the heritability of the disorder.
- **Environmental Factors:** Prenatal exposure to tobacco, alcohol, or drugs, low birth weight, and premature birth are associated with an increased risk of developing ADHD. Environmental toxins, such as lead exposure, have also been linked to higher rates of the disorder.
 - Prenatal Exposure to Substances – Tobacco, alcohol, illicit drugs
 - Toxins – Lead exposure, Polychlorinated Biphenyls (PCBs) and other pollutants
 - Birth conditions – Low birth weight and premature birth
- **Psychosocial Factors:** While not causative, psychosocial factors such as family stress, low socioeconomic status, and educational disparities can exacerbate the symptoms of ADHD or complicate its management.

Pivotal Endpoints in ADHD Clinical Trials

In the context of Attention-Deficit/Hyperactivity Disorder (ADHD), understanding and identifying pivotal endpoints is crucial for the effective assessment of treatment outcomes in clinical trials and practice.

1. Symptom Severity Reduction:

Measured using standardized scales such as the ADHD Rating Scale (ADHD-RS) or the Conners' Parent Rating Scale-Revised (CPRS-R). These scales assess the core symptoms of ADHD, including inattention, hyperactivity, and impulsivity.

2. Improvement in Executive Functioning:

Executive functioning encompasses various cognitive processes including working memory, cognitive flexibility, and inhibitory control. Tests like the Behavior Rating Inventory of Executive Function (BRIEF) are used to assess changes in these areas.

3. Academic Performance:

Specific metrics may include grades, standardized test scores, or teacher assessments of academic behaviors. Improvements in academic performance indicate a significant impact of treatment on a key area of concern for children and adolescents with ADHD.

4. Social Functioning:

Assesses the improvement in interpersonal relationships and social interactions, which are often challenging for individuals with ADHD. Tools such as the Social Skills Improvement System (SSIS) may be utilized.

5. Quality of Life:

Measured through instruments like the ADHD Impact Module (AIM) or the Quality of Life Enjoyment and Satisfaction Questionnaire (Q-LES-Q), this endpoint evaluates the broader impact of treatment on an individual's life satisfaction and daily functioning.

6. Global Functioning:

The Clinical Global Impressions (CGI) scale is often used to provide an overall assessment of the patient's improvement or response to treatment, taking into account all aspects of their ADHD.

Five FDA-Approved Drugs for ADHD

Drug Name	Year of Approval	Sponsor	Mechanism of Action	Therapeutic Effects
Methylphenidate	1955	CIBA (now part of Novartis)	Central nervous system stimulant	- Improves attention and focus - Reduces impulsive behavior and hyperactivity - Improve listening skills and organization
Amphetamine	1996 (Adderall)	Shire Pharmaceuticals (now part of Takeda Pharmaceuticals)	Central nervous system stimulants	- Improves attention, focus, and self-control - Decreasing impulsivity, hyperactivity - Improving attention span, listening skills, and organizational abilities
Atomoxetine	2002	Eli Lilly and Company	Selective norepinephrine reuptake inhibitor	- Increases the ability to pay attention, concentrate, stay focused, and stop fidgeting - Non-stimulant treatment option for ADHD
Lisdexamfetamine	2007	New River Pharmaceuticals Inc./Shire Pharmaceuticals	Prodrug of the central nervous system stimulant dextroamphetamine	- Improve attention, focus, and control behavior problems - Improves listening skills, and organizational abilities - Provide symptom control throughout the day with a single morning dose
Guanfacine (extended-release)	2009	Shire Pharmaceuticals (now part of Takeda Pharmaceuticals)	Selective alpha-2A adrenergic receptor agonist	- Reduce impulsivity, distractibility, and hyperactivity - Non-stimulant properties - Sedative effect

Approved Product Analysis of Ritalin LA in Children with ADHD (Methylphenidate)

Ritalin LA was evaluated in a randomized, double-blind, placebo-controlled, parallel group clinical study in patients with DSM-IV diagnoses of ADHD.

Endpoint	Scales Used	Time Point	Sample Size	Magnitude of Improvement
Pediatric Patients (6-12 years)				
Symptom scores improvement in ADHD	Conners ADHD/DSM-IV Scale for Teachers (CADS-T)	Last week of up to 2 weeks treatment	134 children (Ages 6 to 12)	Mean change: Ritalin LA group: -10.7 points (Improvement) vs. Placebo group: +2.8 points (Worsening)

Approved Product Analysis of ADDERALL XR in ADHD (Amphetamine)

A double-blind, randomized, placebo-controlled, parallel-group study was conducted in patients who met DSM-IV® criteria for ADHD.

Endpoint	Scales Used	Time Point	Sample Size	Magnitude of Improvement
Pediatric Patients (6-12 years)				
Behavioral improvements	Teacher ratings of attention and hyperactivity	3 weeks	N=584	Significant improvements for all ADDERALL XR doses compared to placebo
Adolescent Patients (13-17 years)				
ADHD symptoms improvement	ADHD-Rating Scale IV (ADHD-RS-IV)	4 weeks	N=327 (Primary cohort n=287, Secondary cohort n=40)	Significant improvements in ADHD-RS-IV scores for all doses in primary cohort compared to placebo. Doses >20 mg/day did not confer additional benefit
Adult Patients				
ADHD symptoms improvement	Attention Deficit Hyperactivity Disorder-Rating Scale (ADHD-RS)	4 weeks	N=255	Significant improvements for all doses vs. placebo. Doses >20 mg/day did not confer additional benefit

Approved Product Analysis of STRATTERA in ADHD Treatment (Atomoxetine)

The effectiveness of STRATTERA in the treatment of ADHD was established in randomized, double blind, placebo-controlled studies of patients who met DSM-IV criteria for ADHD.

Endpoint	Scales Used	Time Point	Sample Size	Magnitude of Improvement
Pediatric Patients (6-18 years)				
ADHD symptoms improvement	ADHD Rating Scale-IV-Parent Version (ADHDRS)	8 weeks (Study 1)	N=297 Age: 8-18	Statistically significant improvements at 1.2 and 1.8 mg/kg/day doses; no additional benefit at 1.8 mg/kg/day over 1.2 mg/kg/day
		6 weeks (Study 2)	N=171 Age: 6-16	Statistically significant improvements; effective with once daily morning dose
		9 weeks (Studies 3 & 4)	N=147 N=144 Age: 7-13	Statistically significant improvements; mean final dose approximately 1.6 mg/kg/day
Adolescent Patients (6-15 years)				
Maintenance study for adolescent (6-15 years)			N=292 (STRATTERA) N=124 (Placebo)	Longer times to relapse for continued STRATTERA treatment vs. placebo
Adult Patients (18+ years)				
ADHD symptoms improvement	Conners Adult ADHD Rating Scale (CAARS)	10 weeks (Studies 5 & 6)	N=280 N=256	Statistically significant improvements; mean final dose approximately 95 mg/day

Approved Product Analysis of VYVANSE in ADHD Treatment (Lisdexamfetamine)

A double-blind, randomized, placebo-controlled, parallel-group study was conducted in patients who met DSM-IV criteria for ADHD.

Endpoint	Scales Used	Time Point	Sample Size	Magnitude of Improvement
Children (6–12 years)				
ADHD Symptoms Improvement	ADHD Rating Scale (ADHD-RS)	4 weeks (Study 1)	N=290	All doses superior to placebo; highest dose (70 mg/day) numerically superior but no additional benefit over 50 mg/day
ADHD Behavior	SKAMP-DS	1 week (Study 2)	N=52	Significant improvement from hours 2 to 12 post-dose compared to placebo
ADHD Behavior	SKAMP-Depotment scores	1 week (Study 3)	N=129	Significant improvement across all 7 assessments compared to placebo
Adolescents (13–17 years)				
ADHD Behavior	ADHD Rating Scale (ADHD-RS)	4 weeks (Study 4)	N=314	All doses superior to placebo
Children and Adolescents (6–17 years)				
Short-Term Treatment in ADHD	ADHD-RS-IV, CGI-I	8 weeks (Study 5)	N=336	Significant improvement vs. placebo
Maintenance Treatment in ADHD	Randomized withdrawal	Not specified (Study 6)	N=276	Lower proportion of treatment failures in VYVANSE group
Adults (18–55 years)				
ADHD Symptom Improvement	ADHD Rating Scale (ADHD-RS), PERMP	4 weeks	N=420 (Study 7), N=142 (Study 8)	All doses superior to placebo (Studies 7, 8)
Maintenance Treatment of ADHD	Randomized withdrawal	6 weeks (Study 9)	N=123	Significantly lower proportion of treatment failures in VYVANSE group

Approved Product Analysis of INTUNIV® in ADHD Treatment (Guanfacine (extended-release))

The efficacy of INTUNIV® was studied for the treatment of ADHD in patients who met DSM-IV® criteria for ADHD.

Endpoint	Scales Used	Time Point	Sample Size	Magnitude of Improvement
Pediatric Patients (6-17 years)				
ADHD symptoms improvement	ADHD Rating Scale (ADHD-RS-IV)	8 weeks (Study 1)	N=345 (Ages 6-12)	Statistically significant improvements for 2 mg, 3 mg, and 4 mg INTUNIV® doses compared to placebo.
ADHD symptoms improvement	ADHD Rating Scale (ADHD-RS-IV)	9 weeks (Study 2)	N=324 (Ages 6-12)	Placebo-adjusted changes from baseline were statistically significant for each INTUNIV® dose (1 mg, 2 mg, 3 mg, 4 mg). Dose-responsive efficacy observed.
Pediatric and Adolescent Patients (6-17 years)				
ADHD symptoms improvement as adjunctive therapy to psychostimulants	ADHD Rating Scale (ADHD-RS-IV)	9 weeks (Study 3)	N=455 (Ages 6-17)	Mean reductions in ADHD-RS-IV total scores at endpoint were significantly greater for INTUNIV® + psychostimulant compared to placebo + psychostimulant.

Challenges in Determining Endpoints in ADHD Clinical Trials

1. Variability of Symptoms:

ADHD symptoms can vary significantly among individuals and across different ages and settings, making it challenging to select universal endpoints.

Solution: Personalize treatment endpoints by incorporating a broad set of measures that encompass various symptoms and functional areas. Use both qualitative and quantitative assessment tools tailored to the individual's specific symptomatology and life context.

2. Subjectivity of Assessments:

Many ADHD endpoints are based on subjective reports from patients, parents, or teachers, which can be influenced by personal perceptions, biases, or misunderstandings.

Solution: Implement multi-informant assessment strategies that gather information from various sources. Utilize objective measures, such as neuropsychological tests, alongside subjective reports to provide a balanced view of treatment effects.

3. Comorbidity Complications:

The presence of comorbid conditions, such as anxiety, depression or learning disabilities, can complicate the assessment of ADHD-specific outcomes.

Solution: Conduct thorough initial assessments to identify and differentiate between ADHD symptoms and those of comorbid conditions. Design treatment plans and endpoints that address both ADHD and co-occurring disorders, and monitor these elements separately to accurately assess intervention impact.

4. Long-term vs. Short-term Outcomes:

Balancing the need for immediate symptom relief with long-term functional improvements poses a significant challenge in endpoint selection.

Solution: Establish a dual-focus approach in endpoint selection, incorporating both immediate symptom-related targets and long-term functional goals. Conduct follow-up assessments post-treatment to evaluate sustained effects and adjust care plans as necessary.

Analyzing the Landscape: ADHD Drug Development and Trial Failures

Name of Drug	Clinical Trial Identifier	Findings
Eszopiclone	NCT00856973	Results suggest that Eszopiclone is not effective to reduce latency to persistent sleep on polysomnography after 12 weeks in children aged 6 to 17 years with ADHD-related insomnia
Zolpidem tartrate	NCT00318448	Results suggest that Zolpidem at a dose of 0.25 mg/kg per day to a maximum of 10 mg failed to reduce the latency to persistent sleep on polysomnographic recordings after 4 weeks of treatment in children and adolescents 6 through 17 years of age subjects with attention-deficit/hyperactivity disorder-associated insomnia.
Bupropion	GDCT0153477	Results suggest that bupropion is an effective agent in attention deficit hyperactivity disorder but its effect is less than methylphenidate.
Mydayis ER	NCT03325881	Results suggested that SHP465 at 6.25 mg is not superior to placebo in improving symptoms of ADHD in children aged 6 to 12 years.

Common Failure Points in ADHD Clinical Trials

1. Variability in ADHD Symptom Presentation:

ADHD presents a wide range of symptoms that can vary greatly among individuals and even within the same individual over different settings or times.

2. High Placebo Response:

ADHD clinical trials often encounter a significant placebo effect. This can obscure the true efficacy of the treatment being tested and lead to false conclusions.

3. Participant Adherence and Engagement:

Individuals with ADHD, especially children, may have difficulty adhering to the treatment regimen or protocols due to symptoms such as forgetfulness or lack of focus.

4. Impact of Comorbid Conditions:

Many individuals with ADHD have comorbid psychiatric conditions. Disentangling the effects of the treatment on ADHD from its effects on these comorbid conditions can be challenging.

5. Age-related Challenges:

The expression of ADHD symptoms can change as a person ages, which means that what works for children may not be effective for adolescents or adults, and vice versa.

6. Cultural and Socioeconomic Factors:

Differences in the perception and diagnosis of ADHD can lead to a biased selection of trial participants and may not reflect the general ADHD population.

7. Regulation and Ethics:

Conducting trials on children (a major demographic for ADHD) involves strict ethical and regulatory considerations, which can limit the scope of research and complicate data collection.

8. Attrition Rates in Long-term Studies:

ADHD trials, especially long-term studies, often face high dropout rates due to the chronic nature of the disorder and the challenges in maintaining participant engagement over time.

Safety Concerns and Standard of Care

Safety Concerns

The pharmacological treatment of ADHD, involving stimulants and non-stimulant medications, brings several safety considerations to the fore

- **Cardiovascular Risks:** Stimulant medications, such as methylphenidate and amphetamines, can elevate heart rate and blood pressure. Although significant cardiovascular events are rare, they underscore the need for careful patient screening and monitoring, especially in individuals with pre-existing heart conditions.
- **Growth Suppression:** Long-term use of stimulant medications has been associated with growth suppression in children. Monitoring height and weight periodically is essential to assess the risk-benefit ratio.
- **Substance Misuse:** Given their psychoactive properties, there is a potential for misuse and diversion of stimulant medications. Strategies to mitigate this risk include using tamper-resistant formulations and closely monitoring prescription refills and usage patterns.

Standard of Care

The standard of care for ADHD involves a multifaceted approach tailored to the individual's symptoms, age, and personal circumstances. This approach combines medication, behavioral interventions, and educational support:

- **Medication Management:** Stimulants are first-line treatments for many patients with ADHD. Non-stimulant options or combinations thereof may be preferable based on the patient's health history and response to treatment. Medication management should include regular follow-ups to assess efficacy, side effects, and adherence.
- **Behavioral Therapies:** Behavioral interventions, such as cognitive-behavioral therapy (CBT), are effective in managing ADHD symptoms and improving overall functioning. Parental training programs and social skills training are also integral, particularly for children and adolescents.
- **Educational Support and Accommodations:** Collaboration with educational institutions to provide necessary accommodations is critical for addressing the academic challenges associated with ADHD.

Enhancing Clinical Trial Protocols: Towards FDA Approval

Securing approval from the Food and Drug Administration (FDA) for new ADHD treatments requires meticulous planning and execution of clinical trials. The complex nature of ADHD, characterized by diverse symptoms and high comorbidity rates, presents unique challenges in trial design and implementation.

1. Integration of Neurocognitive Testing:

Incorporate standardized neurocognitive tests that measure attention, executive function, and working memory.

2. Customized Behavioral Interventions:

Design trials that include tailored behavioral interventions addressing common ADHD-related challenges.

3. Technology-Enhanced Adherence Strategies:

Utilize technology, such as wearable devices, or online platforms, to improve medication adherence and trial participation.

4. Parent Involvement:

Actively involve parents and caregivers in the trial process, providing them with resources and strategies to support the participant's adherence & engagement.

5. Sensory & Environmental Modifications:

Adapt trial environments to minimize distractions and reduce sensory overload, which can impact participation & performance.

6. Longitudinal Follow-up:

Extend the duration of follow-up periods to assess the long-term efficacy and safety of treatments, considering the chronic nature of ADHD.

7. Addressing Comorbid Conditions:

Develop protocols that specifically address the high prevalence of comorbid psychiatric conditions within the ADHD population.

8. Stakeholder Feedback:

Engage with ADHD patients, parents, educators, and advocacy groups during the trial design to ensure the study addresses relevant and meaningful outcomes.

Notable Key Opinion Leaders in ADHD Research

Name	Specialty	Designation	Location	Brief Bio
Kristi R Griffiths B.Psych (Hons), PhD	Neurology; Psychology	Snr Research Fellow, Westmead Institute for Medical Research	NSW, Australia	Kristi Griffiths is a Senior Research Fellow at the Westmead Institute for Medical Research, focusing on neurodevelopmental and eating disorders within the neuroimaging team at the Brain Dynamics Centre. Griffiths' focus extends to the study of impulse control, ADHD, and eating disorders, employing advanced neuroimaging-based connectomic methodology to address the heterogeneity of these disorders and their treatments.
Dr Noel E Cranswick MBBS B Med Sc LLB FRACP	Pediatric Medicine;Clinical Pharmacology	Associate Professor, University of Melbourne	VIC, Australia	Dr. Noel Cranswick currently serves as a general pediatrician and director of clinical pharmacology at the Department of General Medicine at the Royal Children's Hospital, Melbourne, Australia. Dr. Cranswick evaluates new drug applications for the Australian Therapeutic Drugs Administration and has contributed to the selection of Essential Medicines for the World Health Organization, as well as evaluating therapies for the European Union
Dr Michelle Ball PhD (Hons) Bachelor of Arts (Hons)	Neuropsychology	Associate Professor, Victoria University	VIC, Australia	Dr. Michelle Ball is an Associate Professor and Deputy Head of the Psychology discipline at Victoria University. Her research interests span cognitive psychology, particularly executive functioning and assessment, microbiome-gut-brain interactions, cognitive processing during sleep, and human behavior in fire.
Daryl Efron MBBS FRACP	Pediatric Medicine	Associate Professor, The Royal Children's Hospital	VIC, Australia	Associate Professor Daryl Efron is a pediatrician at the Royal Children's Hospital, Melbourne, with a rich experience spanning over 30 years. Associate Professor Efron is notably active in research, focusing on finding better treatment methods for children with developmental disorders such as autism, ADHD, and Tourette syndrome, aiming to enhance the quality of life for both the children and their families
Dr Christopher (Chris) Lamb BMBS, FRACP	Neurology; Pediatric Medicine	Pediatrician, Southside Kids	SA, Australia	Dr. Christopher Lamb is a general pediatrician at Southside Kids with expertise in developmental and behavioral pediatrics. He sees children ranging from 0 to 18 years and has participated in ADHD research projects.

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If you would like further information on how iNGENū CRO can assist you to conduct your clinical trial, please contact Dr Sud Agarwal or Adam Moodie:



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