

---

**The Child Health and Illness Profile as a measure of health-related quality of life in stimulant-treated children and adolescents with ADHD**

---

T. Banaschewski<sup>1</sup>, C. Soutullo<sup>2</sup>, M. Lecendreux<sup>3</sup>, M. Johnson<sup>4</sup>, A. Zuddas<sup>5</sup>, P. Hodgkins<sup>6</sup>, B. Adeyi<sup>7</sup>, L.A. Squires<sup>8</sup>, D.R. Coghill<sup>9</sup>

<sup>1</sup>Child and Adolescent Psychiatry and Psychotherapy, University of Heidelberg, Mannheim, Germany ; <sup>2</sup>Child and Adolescent Psychiatry Unit, University of Navarra Clinic, Pamplona, Spain ; <sup>3</sup>Paediatric Sleep Centre and National Reference Centre for Orphan Diseases: Narcolepsy Idiopathic Hypersomnia and Kleine-Levin Syndrome, Robert-Debré University Hospital, Paris, France ; <sup>4</sup>Child Neuropsychiatry Unit, Queen Silvia Children's Hospital, Gothenburg, Sweden ; <sup>5</sup>Department of Biomedical Sciences, University of Cagliari, Cagliari, Italy ; <sup>6</sup>Global Health Economics and Outcomes Research, Shire Development LLC, Wayne, USA ; <sup>7</sup>Global Biostatistics, Shire Development LLC, Wayne, USA ; <sup>8</sup>Global Clinical Development and Innovation, Shire Development LLC, Wayne, USA ; <sup>9</sup>Division of Neuroscience, University of Dundee, Dundee, United Kingdom

---

## Introduction

The Child Health and Illness Profile-Child Edition: Parent Report Form (CHIP-CE:PRF) is a generic measure of child health-related quality of life (HRQoL). Scores in the five domains and 12 subdomains are standardized to T-scores (mean=50, SD=10), based on US community data.

## Objective

Evaluate CHIP-CE:PRF results from two studies of lisdexamfetamine dimesylate (LDX) in children and adolescents with ADHD.

## Methods

Patients' parents or guardians completed CHIP-CE:PRF assessments at baseline, and weeks 4 and 7 of SPD489-325, a 7-week randomized, placebo-controlled trial incorporating a reference treatment (osmotic-release oral system methylphenidate; OROS-MPH). The Achievement domain was pre-specified as the primary HRQoL outcome. Statistical comparison of LDX versus OROS-MPH was not pre-specified. In SPD489-326, CHIP-CE:PRF assessments were performed in the  $\geq 26$ -week open-label period and the subsequent 6-week randomized-withdrawal period.

## Results

Pre-treatment CHIP-CE:PRF T-scores were  $\geq 1$  SD below 50 in Achievement, Risk Avoidance, Satisfaction and Resilience. In SPD489-325, LDX and OROS-MPH were both significantly more effective than placebo in these four domains, but not in Comfort. Effect sizes were largest ( $p < 0.001$ ) in Achievement (LDX, 1.280; OROS-MPH, 0.912) and Risk Avoidance (LDX, 1.079; OROS-MPH, 0.948). In SPD489-326, T-scores were improved or stable in the open-label period. In the randomized-withdrawal period, LDX was significantly more effective than placebo ( $p < 0.001$ ) in Achievement, Risk Avoidance and Satisfaction, with effect sizes of 0.696, 0.829 and 0.636, respectively.

## Conclusions

Short-term LDX or OROS-MPH treatment led to improved HRQoL scores. These benefits were maintained during long-term LDX treatment, and HRQoL scores declined following treatment withdrawal.

Supported by funding from Shire.