

Bubs Australia Selects Validcare as CRO for Infant Formula Growth Monitoring Study for U.S. Market Authorization

Validcare is conducting a Growth Monitoring Study (GMS) for Bubs Australia providing visibility and control to complete study on time, and on budget.



DENVER, CO, UNITED STATES, September 19, 2023 /EINPresswire.com/ -- [Validcare](#) announces it contracted with Bubs Australia to run its [Growth Monitoring Study](#) (GMS) of 440 healthy term infants. The study's purpose is to demonstrate acceptable growth and tolerance for three of its products to achieve permanent U.S. market authorization from the U.S. Food and Drug Administration (FDA) while it continues to import under the FDA's enforcement discretion policy.



Validcare's performance-based model, plus decades of infant formula experience, provides us with confidence in their management of this large-scale study."

Richard Paine, COO Bubs Australia

Richard Paine, COO of Bubs Australia said, "Validcare's performance-based model, plus decades of infant formula experience, provides us with confidence in their management of this large-scale study. Their approach automates almost all study interactions and data collection from recruitment through database lock, versus traditional methods."

Validcare's smart data capture system proactively directs

investigators to perform additional measurements when variances are out of protocol limits, then calculates a final input.

"The ability for clinical research investigators to enter data electronically into Validcare's clinical study platform enhances protocol compliance," said Michael B. Montalto, PhD scientific and regulatory advisor for Bubs Australia. "This 'smart data capture' system improves data integrity and makes it easy for clinicians to accurately enter growth data and for parents to report product tolerance from home."

This nationwide study measures growth and tolerance of healthy-term infants consuming Bubs'

infant formulas, monitored by healthcare professionals at 13 clinical research sites with additional input from parents and caregivers. The study evaluates all three of the Bubs Stage 1 formulas in the market (one goat's milk and two cow's milk products), and a commercially available formula as the control. Additionally, the study contains a breastfeeding group for reference.

Rod Nuss, COO of Validcare added, "This is one of the largest infant formula studies on record. We are excited to earn the trust of Bubs Australia to gather the data necessary for the FDA. Our team, together with the investigators, is well positioned to deliver high quality data on budget and in advance of the FDA's September 2024 deadline."

The study is approved by Advarra's Institutional Review Board and registered on clinicaltrials.gov. For more information on eligibility for the Bubs Growth Monitoring Study, please visit validcare.com/bubs-gms.

About Validcare

Validcare is a high-performance Contract Research Organization (CRO) uniquely skilled at de-risking the execution of clinical studies for pharma, biotech and medical device companies, spanning all therapeutic areas. Its revolutionary approaches give sponsors unmatched visibility and control to complete studies on time, on budget, and with high data integrity. Founded by experts with more than 30 years of executive-level industry experience, Validcare is a trusted advisor and strategic business counsel to its sponsor clients, helping to bring life-changing products to market.

For more information, visit validcare.com or call 844-825-4322.

About Bubs Australia (ASX:BUB)

Bubs Australia is on a mission to nourish new generations of happy Bubs, with clean label nutritional products that provide the foundation for setting up a lifetime of good eating habits. Founded in 2005 and long trusted by families throughout APAC, Bubs entered the U.S. market first with its toddler formulas in 2021 and then with its infant formulas in 2022 at the height of the U.S. formula crisis. Today, Bubs is the #1 Goat Milk Infant and Toddler Formula in the U.S. Other products include Bubs 365 Day Organic Grass Fed Cow Milk Formula and Bubs Supreme Infant Formula. Bubs can be purchased at aussiebubs.com and major retailers including Target, Amazon and Walmart. Visit aussiebubs.com for more information.

Kim Hightower

Validcare, LLC

+1 844-825-4322

[email us here](#)

Visit us on social media:

[Twitter](#)

[LinkedIn](#)

This press release can be viewed online at: <https://www.einpresswire.com/article/656263407>

EIN Presswire's priority is source transparency. We do not allow opaque clients, and our editors try to be careful about weeding out false and misleading content. As a user, if you see something we have missed, please do bring it to our attention. Your help is welcome. EIN Presswire, Everyone's Internet News Presswire™, tries to define some of the boundaries that are reasonable in today's world. Please see our Editorial Guidelines for more information.

© 1995-2023 Newsmatics Inc. All Right Reserved.