

# PediCAP trial completes recruitment investigating child-friendly treatment for severe community-acquired pneumonia

*The PediCAP team is pleased to report that the 1100 patients required for the main trial in this study have now been recruited.*

PADOVA, ITALY, September 1, 2023 /EINPresswire.com/ -- PediCAP is an innovative, [EDCTP](#)

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*Carlo Giaquinto, Penta Foundation President*

funded clinical trial, using a novel durations design led by the MRC Clinical Trials Unit that is studying the optimal drug, dose and duration of oral step-down antibiotics for children admitted to hospital with [severe community-acquired pneumonia](#). Children included in the trial are aged between 2 months and 6 years and have been recruited in district and tertiary hospitals in Mozambique, South Africa, Uganda, Zambia, and Zimbabwe.

Carlo Giaquinto, President of [Penta](#) states that “As the coordinators of the PediCAP trial, Penta is very pleased with the successful completion of participant recruitment. This is a significant milestone for the trial, and

demonstrates the effectiveness and dedication of the trial staff at participating sites. Pneumonia poses a serious health threat to children but I believe that through the analysis of the PediCAP-A trial results, meaningful conclusions will be drawn that could advance treatment options for children with severe and very severe pneumonia.”

Pneumonia affects children and families globally and is one of the leading causes of death in children under 5, especially in Southern Asia and Africa. There is an urgent need for effective and simple treatment options for children with pneumonia. Though antibiotics are key to managing childhood pneumonia, current WHO recommendations are that children hospitalised for severe community-acquired pneumonia only be given antibiotics intravenously, which means that children must remain hospitalised for the entire duration of the treatment course, which affects the well-being of children and their families and places a burden on healthcare facilities. This also increases the risk of antimicrobial resistance and hospital-acquired infections.

Martha Tholanah, PediCAP Zimbabwe Community Advisory Board member had this to say about

the PediCAP trial, “Managing children at home is very good for the mental health of parents because they can be around their children. It also reduces the cost of frequent visiting that parents may need to do when their children are hospitalised.”

PediCAP evaluates the safety and efficacy of an early step-down from intravenous to oral antibiotics, comparing different durations of oral amoxicillin to co-amoxiclav and could establish a more convenient and potentially equally effective alternative to the WHO intravenous treatment recommendations. Sandoz, a global generic and biosimilar medicines company based in Switzerland, donated a novel paediatric dispersible tablet formulation of co-amoxiclav 7:1 to support PediCAP’s main trial. Dispersible tablets (DT) is the WHO’s preferred formulation of medicines for young children and a DT formulation for amoxicillin-clavulanate has been included in the 2023 Essential Medicines List for Children.

Professor Mike Sharland, Chief Investigator of PediCAP says, “The full recruitment to the PediCAP-A trial through the challenges of Covid-19 has been a remarkable success, reflecting a huge effort of all the teams involved, including all the families with children recruited to the study, the clinical teams in our partner countries and all of the work by the many research staff that have worked together for this major achievement.”

This significant milestone brings PediCAP A results closer, with the main clinical outcome results of the trial supported by planned pharmacokinetic, microbiology, and health economic analyses. The PediCAP B trial, which compares other novel formulations of co-amoxicillin is still recruiting and is planned to complete in 2024.

#### About PediCAP

PediCAP is part of the EDCTP2 programme supported by the European Union (grant number RIA2017MC – 2023 – PediCAP) and is coordinated by Fondazione Penta ETS (Italy).

The PediCAP consortium comprises experts in paediatric clinical trials and clinical partners from Europe and Africa, namely; Universidade Eduardo Mondlane, Global Antibiotic Research and Development Programme, University of Oxford, Swiss Tropical and Public Health Institute, University of Antwerp, University College of London, Kwa-Zulu-Natal Research Institute for TB-HIV, University Teaching Hospital Zambia, University of Zimbabwe College of Health Sciences Clinical Trial Research Centre, Makerere University, University of Cape Town, Wits Health Consortium, St George’s University and Penta.

#### About Penta

Penta is an international independent scientific network devoted to advancing research on optimising the prevention, diagnosis and treatment of infectious diseases in children, globally.

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