

External factors affecting recruitment in a global paediatric pneumonia trial: lessons learned from PediCAP



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Introduction

- PediCAP is an EDCTP-funded clinical trial (ISRCTN63115131) aiming to determine optimal duration and dose of co-amoxiclav and amoxicillin in children with severe pneumonia
- The recruitment target was set to 1100 in the main trial, PediCAP-A, and 120 in the pharmacokinetic substudy, PediCAP-B.

Methods

- Recruitment occurred across thirteen sites in Uganda, Zambia, Zimbabwe, South Africa and Mozambique.
- Virtual monitoring of recruitment was led by the Medical Research Council Clinical Trials Unit (MRC-CTU).
- Sites communicated recruitment challenges to the MRC-CTU

Results

- External factors affecting recruitment are summarised in Figure 1
- Responses to these challenges included no-cost extensions, altered training delivery, recruitment pauses and one site closure
- Recruitment varied from site to site, demonstrated in Figure 2
- Despite these challenges, the recruitment target for PediCAP-A was reached in August 2023. PediCAP-B recruitment is ongoing.



PediCAP-A Recruitment by site

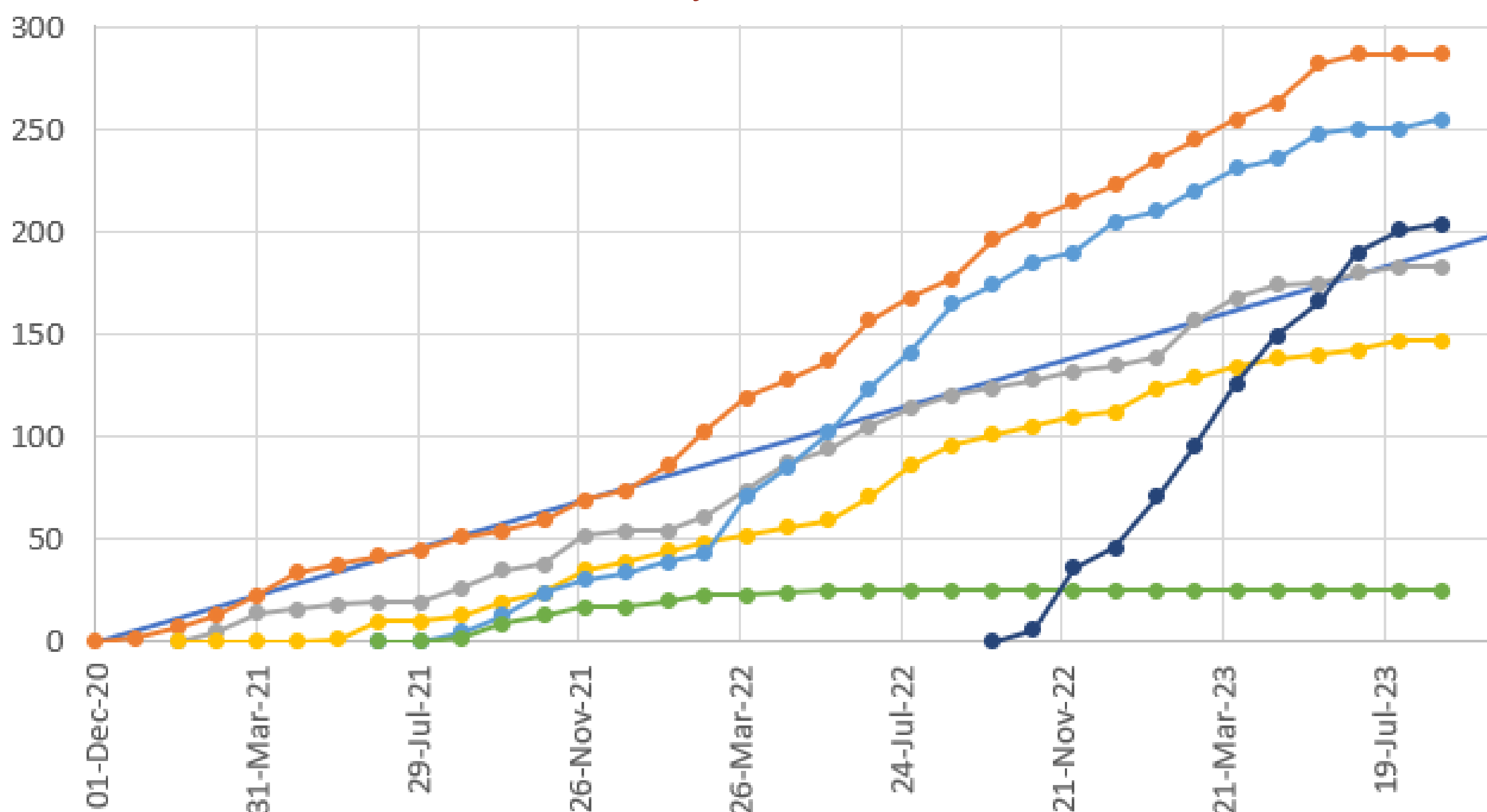


Figure 2: PediCAP-A recruitment by site, anonymised. Satellite site numbers are included under the primary site line. Overall projected recruitment per site is indicated by the straight blue line.

Figure 1: Summary of recruitment challenges. Covid-19 pandemic-related challenges are shown in green.

Conclusions

- A range of external factors can impact trial recruitment that require a rapid response from sites and trial coordinators
- Close communication between sites and the MRC-CTU was vital in order to understand these challenges and formulate an appropriate response
- A pragmatic approach to unforeseen events was required to reach the recruitment target