

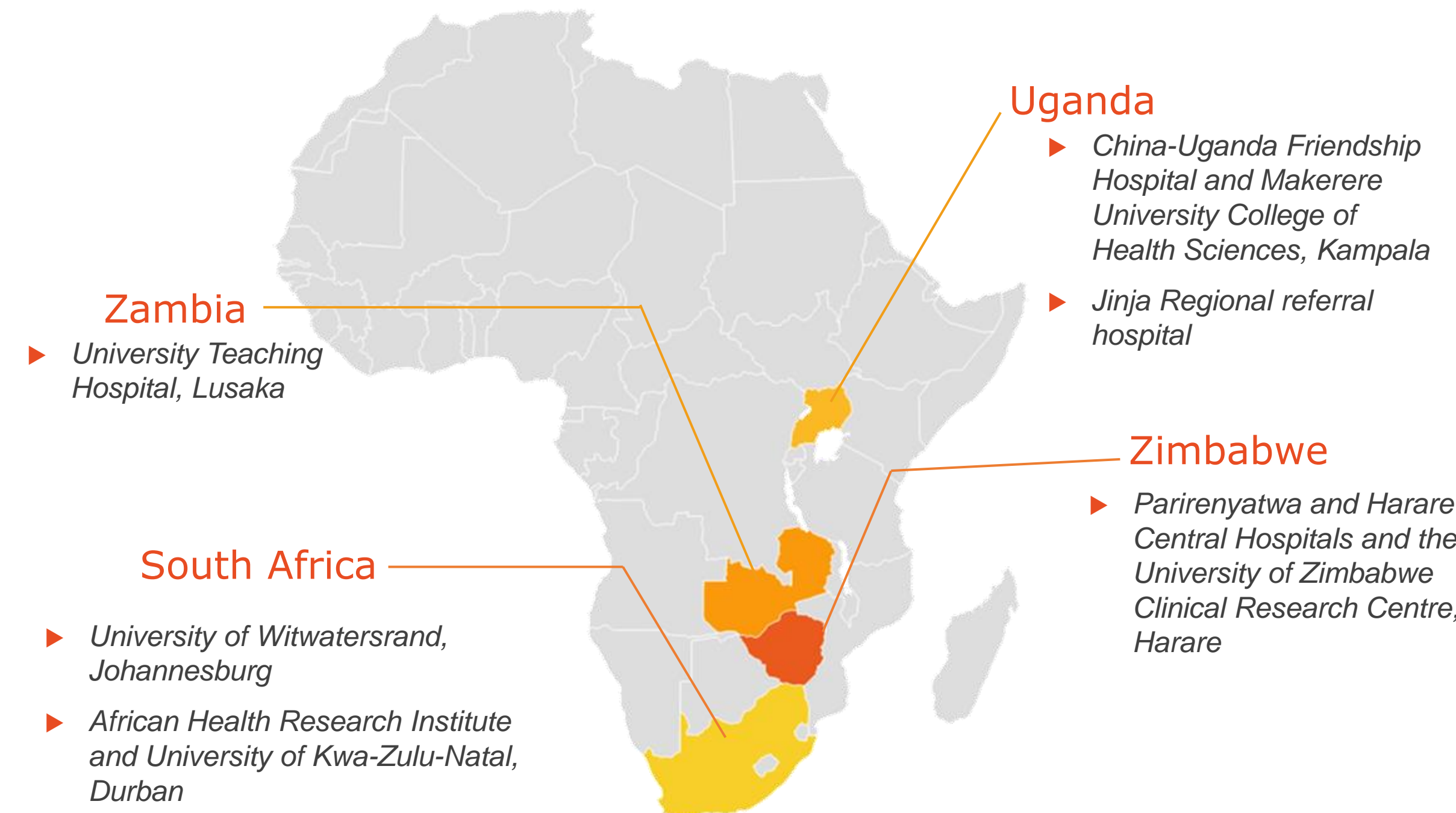
# Navigating the COVID-19 Pandemic for Participant Recruitment and Follow-up: Experiences from the PediCAP Clinical Trial Consortium

Andrew Kiggwe,<sup>1,2</sup> Damalie Nalwanga<sup>1,3</sup>, Abner Tagoola<sup>4</sup>, Shabir Madhi<sup>5</sup>, David P. Moore<sup>5</sup>, Moherndran Archary<sup>6</sup>, Veronica Mulenga<sup>7,8</sup>, Hilda Angela Mujuru<sup>9,10</sup>, Jahit Sacarlal<sup>11</sup>, W. Chris Buck<sup>11,12</sup>, Muhammad Sidat<sup>11</sup>, Hanh Nguyen<sup>13</sup>, Farjana Haque<sup>13</sup>, Emily Dennis<sup>13</sup>, Michelle Clements<sup>13</sup>, Brendan Murphy<sup>13</sup>, Ben Spittle<sup>13</sup>, Francesca Viero<sup>14</sup>, Julia Bielicki<sup>15</sup>, Victor Musiime<sup>1,3</sup>, Mike Sharland<sup>15</sup>

<sup>1</sup>Makerere University Lung Institute, College of Health Sciences, Kampala, Uganda, <sup>2</sup>China Uganda Friendship Hospital – Naguru, Kampala, Uganda, <sup>3</sup>Makerere University, College of Health Sciences, Department of Pediatrics and Child Health, Kampala, Uganda, <sup>4</sup>Jinja Regional Referral Hospital, Jinja, Uganda, <sup>5</sup>Chris Hani Baragwanath Academic Hospital and University of the Witwatersrand, Johannesburg, South Africa, <sup>6</sup>Africa Health Research Institute, King Edward VIII Hospital, Durban, South Africa, <sup>7</sup>University Teaching Hospital, Lusaka, Zambia, <sup>8</sup>Chawama Level 1 Hospital, Lusaka, Zambia, <sup>9</sup>University of Zimbabwe Clinical Research Centre, Harare, Zimbabwe, <sup>10</sup>Chitungwiza Hospital, Harare, Zimbabwe, <sup>11</sup>Universidade Eduardo Mondlane Faculdade de Medicina, Maputo, Mozambique, <sup>12</sup>University of California Los Angeles David Geffen School of Medicine, Los Angeles, USA, <sup>13</sup>Medical Research Council Clinical Trials Unit at University College London, London, UK, <sup>14</sup>Fondazione PENTA ONLUS, Padova, Italy, <sup>15</sup>St George's University of London, UK

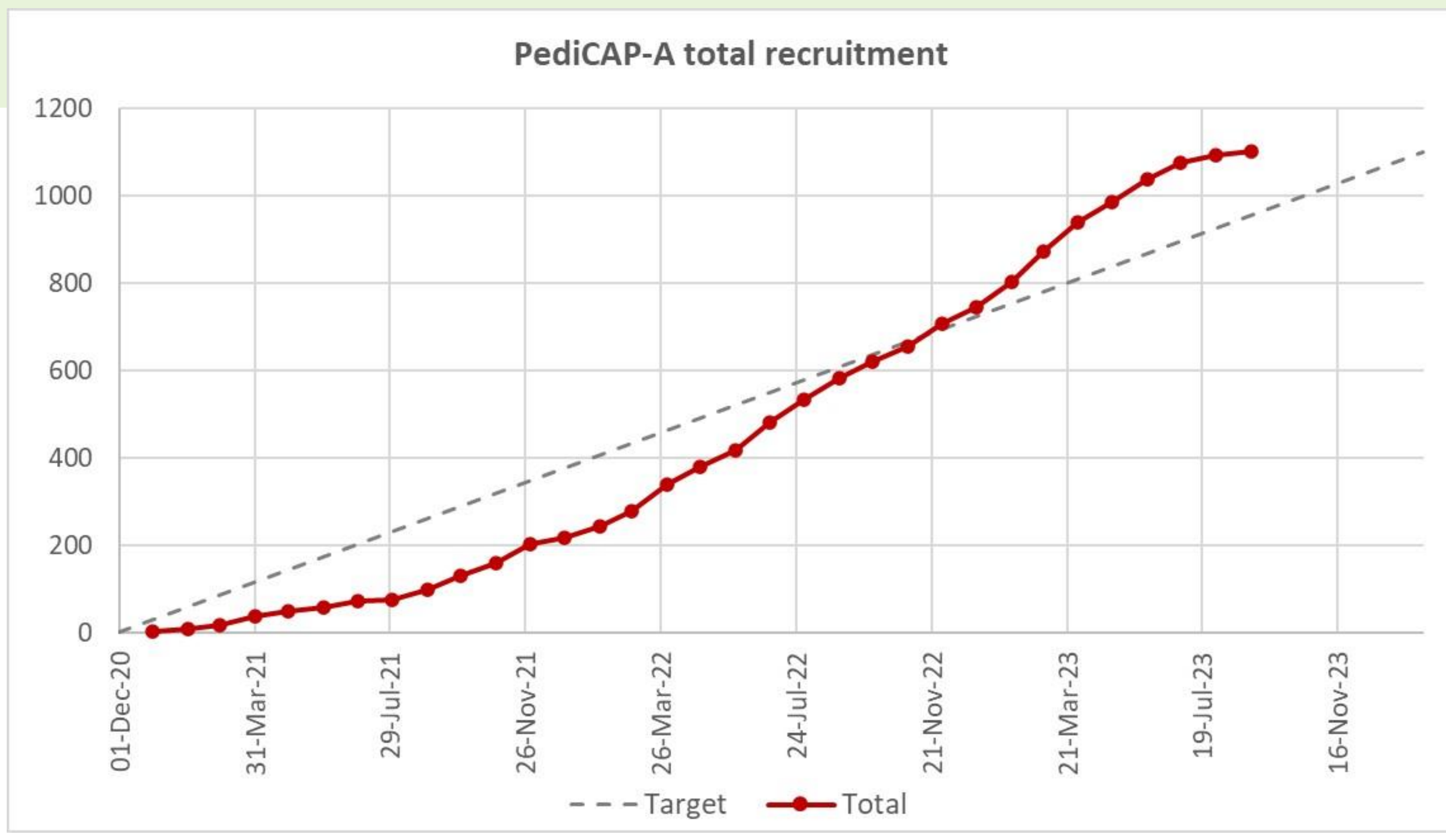
## BACKGROUND

- COVID-19, first reported in Wuhan, China in December 2019, was declared a pandemic in March 2020, resulting in restrictions of movement of people and goods worldwide.
- This affected every aspect of life, including the conduct of clinical trials.
- We highlight the challenges faced by the PediCAP consortium and how the team navigated them.



## METHODS

- The PediCAP consortium is composed of 14 partners (<https://projectpedicap.org/the-consortium/>) in Africa and Europe.
- The EDCTP-funded clinical trial (ISRCTN63115131) is enrolling children aged 2 months to 6 years with pneumonia in Mozambique, Uganda, South Africa, Zambia and Zimbabwe.
- Participant recruitment started in December 2020, during the COVID-19 pandemic; and by end of August 2023, 1100 of the targeted 1100 participants (100%) had been enrolled into the main trial; PediCAP-A.
- Enrollment into PediCAP-B is underway; 45.8% complete.
- The challenges faced by the clinical sites, and measures taken to mitigate them, were obtained from minutes of monthly teleconferences and interviews with site staff, and summarized in themes.



## RESULTS

- The following were reported as challenges and their mitigating measures:

Challenge	Mitigating measure
<ul style="list-style-type: none"> <li>• Delays in obtaining ethical and regulatory approvals</li> </ul>	<ul style="list-style-type: none"> <li>• Regulatory bodies adopted paperless submissions, virtual review meetings, and used online tools to interact with applicants.</li> </ul>
<ul style="list-style-type: none"> <li>• Slow recruitment of participants resulting from reduction in numbers of patients attending hospitals</li> </ul>	<ul style="list-style-type: none"> <li>• Was solved by adding a partner and satellite sites</li> <li>• A no-cost extension of the project was made to allow further recruitment</li> </ul>
<ul style="list-style-type: none"> <li>• Delay of site initiation, protocol training, procurement of trial drugs and clinical trial monitoring</li> </ul>	<ul style="list-style-type: none"> <li>• The sponsor adopted virtual platforms and local monitors</li> </ul>
<ul style="list-style-type: none"> <li>• A need to protect staff from contracting COVID-19</li> </ul>	<ul style="list-style-type: none"> <li>• Country-specific COVID-19 risk management plans were developed and implemented</li> </ul>

## CONCLUSION

COVID-19 impeded smooth progress of PediCAP trial activities. However, a joint and collaborative effort was key in navigating the challenges.

## ACKNOWLEDGEMENTS

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