

Item 29.1: Ancillary analyses

Highlight unanswered and new questions, and discuss potential future research

Title and abstract	1a.1	Title and structured abstract
Introduction	6.1	Background and rationale <i>Prevalence/incidence</i>
	6.2	Background and rationale <i>Efficacy/effectiveness</i>
	6.3	Background and rationale <i>Research question or aim</i>
Methods	12a.1	Eligibility criteria <i>Justification for including multiple age groups</i>
	12a.2	Eligibility criteria <i>Age-appropriate trial information</i>
	13.1	Intervention and comparator <i>Dose/formulation</i>
	13.2	Intervention and comparator <i>Intervention delivery</i>
	14.1	Outcomes
	15.1	Harms
Results	25.1	Baseline data
	28.1	Ancillary analyses
Discussion	29.1	Interpretation

Key elements for reporting this item:

- ✓ • What are unanswered questions about other paediatric age groups, other developmental stages, and short term or long term effects on development
- ✓ • What are unanswered questions specific to children/adolescents, with explanation of the reasons for not clarifying these issues within this trial
- ✓ • What are questions arising from the current study, especially those with potential impacts on safety, short term or long term effects on development, implying limitations for paediatric use
- ✓ • Next steps in the evaluation of the intervention studied before it can be recommended for clinical practice or in other paediatric age groups or other developmental stages
- ✓ • Need for long term (developmental) follow up studies, future trial phases, further preclinical studies.

Examples:

- ✓ *“The mean time in the target glucose range was 10 percentage points higher and the mean glycated hemoglobin level was 0.4 percentage points (4 mmol per mole) lower in the closed-loop group than in the control group at 12 months, but these results did not reach the pre-specified significance thresholds, and it is possible that a greater improvement in glucose control with attainment of normoglycemia could prevent the decline in C-peptide secretion.^[reference] Further research is needed to definitively rule out a role of glycemic burden in the decline of C-peptide secretion. In addition, the greater mean time below the target glucose range and greater mean glycemic coefficient of variation observed in the closed-loop group may have reduced beta-cell viability.^[reference]”*

✓ Boughton CK, Allen JM, Ware J, et al; CLOuD Consortium. Closed-Loop Therapy and Preservation of C-Peptide Secretion in Type 1 Diabetes. *N Engl J Med* 2022;387:882-93. doi:10.1056/NEJMoa2203496.

✓ See the [E&E](#) for more examples.

