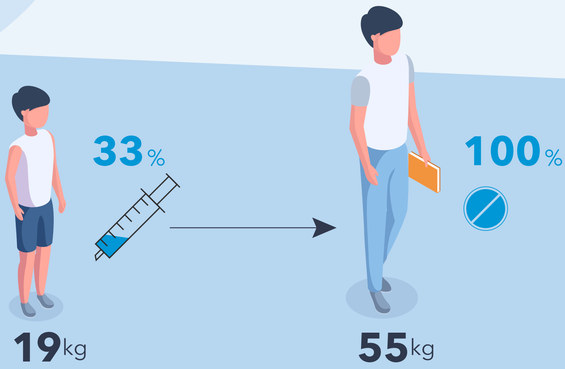
Pharmacokinetics of riociguat in children with pulmonary arterial hypertension (PAH)

PAH in children causes substantial morbidity and mortality.

Riociguat is a drug approved for the treatment of adult patients with PAH, but not yet for children.

The **PATENT-CHILD** study investigated the pharmacokinetics and safety of riociguat in children aged **≥6 to <18 years** with **PAH**.

The study concluded that a **bodyweight-adjusted dose** of riociguat should be used to achieve a **similar exposure** to that observed in **adults** with PAH.



PATENT-CHILD dosing scheme

RIOCIGUAT initiated at 1.0 mg equivalent

The suspension volumes (mL) shown below are given three times daily, individually adjusted up to a maximum dose of 2.5 mg equivalent

Equivalent dose (based on a suspension containing 0.15 mg/mL riociguat)	0.5 mg	1 mg	1.5 mg	2 mg	2.5 mg
Bodyweight					
≥14 to <16kg	1.00mL	1.75mL	2.75mL	3.75mL	4.75mL
≥16 to <18kg	1.00mL	2.00mL	3.00mL	4.25mL	5.00mL
≥18 to <20kg	1.00mL	2.25mL	3.25mL	4.50mL	5.50mL
≥20 to <25kg	1.25mL	2.50mL	3.75mL	5.00mL	6.50mL
≥25 to <30kg	1.50mL	3.00mL	4.25mL	6.00mL	7.50mL
≥30 to <35kg	1.75mL	3.25mL	5.00mL	6.50mL	8.50mL
≥35 to <40kg	1.75mL	3.75mL	5.50mL	7.00mL	9.50mL
≥40 to <50kg	2.25mL	4.50mL	6.50mL	9.00mL	11.00mL
≥50*kg	3.25mL	6.50mL	10.00mL	13.50mL	16.50mL

*In children >50 kg, the adult dose in tablet form is recommended.