



Product profile:

Heat stable sublingual oxytocin fast-dissolving tablet (FDT)



PATH/Patrick McKern

- **What is the need?** Postpartum hemorrhage (PPH) is the most significant contributor to maternal mortality and morbidity worldwide.
- **What is the product?** Needle-free, heat-stable oxytocin in a fast-dissolving tablet (FDT) form to prevent PPH .
- **PATH's role:** (Technology developer)

Donor: Saving Lives at Birth (SLAB)

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Partners: None

Highlights

- PATH developed a heat-stable formulation of oxytocin fast-dissolving tablet (FDT) by conducting freeze-drying in blisters.
- The sublingual oxytocin tablet is robust with good handling properties; can be packaged in blisters or bulk packaging
- The FDT disintegrates in human saliva in under 10 seconds.
- The oxytocin in the FDT is heat stable under elevated temperature conditions, maintaining acceptable oxytocin content at 37°C/75% relative humidity (RH) at the end of 12 months
- Pharmacokinetic evaluation of oxytocin FDTs in female pigs shows sublingual absorption of oxytocin, although the plasma levels observed are *lower* than those obtained with intramuscular (IM) administration.



Photo credit: PATH/Patrick McKern

Next Steps

- Seeking funding and partner for conducting exploratory pharmacokinetic study in adult non-pregnant women to validate the proposed approach for administration of oxytocin