

# Reducing the Risk of Medical Device Tubing Misconnections

ENFit<sup>®</sup> Low Dose Tip Syringe Review

Q2 2016



# ENFit and Dose Accuracy Background

- ⦿ “Reducing the risk of (tubing) misconnection requires a complete design change with correlating standards established and adopted worldwide across the industry” (GEDSA website)
  - This is achieved through ISO 80369-3 for enteral connections
- ⦿ Dose delivery accuracy (*which includes the entire system*) ensures that the correct dose is prepared and administered to the patient
- ⦿ There is no standard to reference for dose delivery accuracy applicable to enteral syringes and/or administration systems
- ⦿ Non-enteral reference points, such as hypodermic syringe performance standards (ISO 7886), provide information on container measurement accuracy, but not delivery accuracy

# Dose Accuracy Concerns Raised

## ⦿ Clinicians:

- Raised concerns on the dosing accuracy of small volume ENFit<sup>®</sup> syringes, due to their reverse gender orientation
- Indicated a dosing accuracy expectation of  $\pm 10\%$  for a target volume of 0.2mL when delivered from a 1mL syringe

## ⦿ Industry:

- There is no global standardized test (ISO, AAMI, ASTM, EN, etc.) for manufacturers to use to evaluate dosing accuracy for syringes
- In absence of a standardized test, no baseline data existed for comparison

# Performance Testing

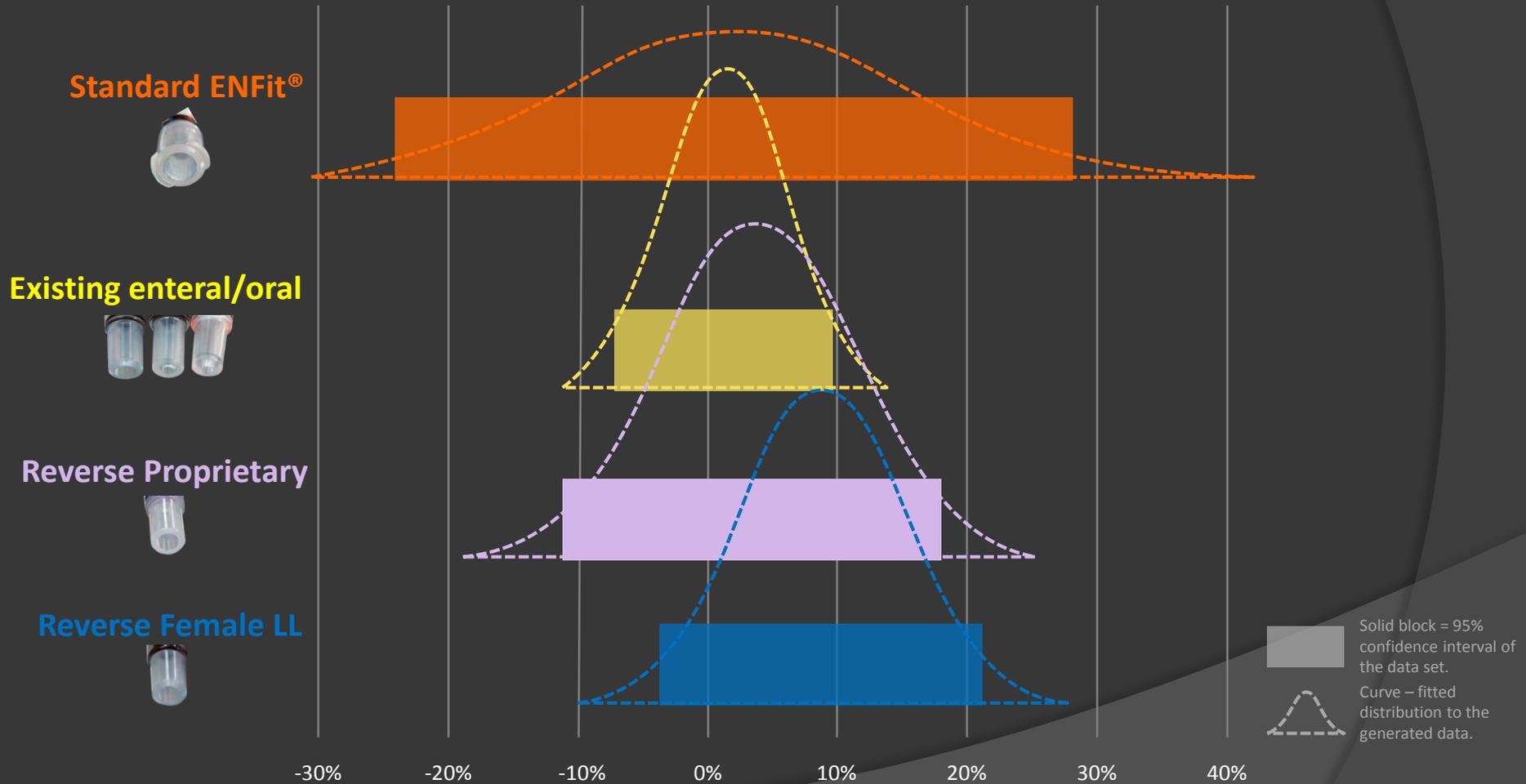
- GEDSA members assessed the ability of the standard ENFit® syringe to meet a +/-10% delivery accuracy and determined that syringe sizes of 5 mL or smaller may require a “low dose tip” ENFit® connector design to meet this target
- Performance testing was then conducted by a third-party, accredited test lab. The following enteral syringe types were evaluated to determine the performance of the low dose design and to establish a baseline for the performance of existing syringes:
  - Leading brands of existing enteral/oral syringes (*all male tip*)
  - Female Luer lock (*reverse system used in the UK*)
  - Proprietary reverse system syringes currently marketed
  - Standard ENFit® syringe tip
  - Proposed ENFit® low dose tip syringe

OBJECTIVE: Address delivery accuracy concerns raised by clinicians and determine the baseline performance of existing enteral syringes/systems

Results were submitted to the FDA to support 510(k) submissions for the low dose tip design

# Small Volume Dose Accuracy of Common Enteral/Oral Tip Syringes

*(Delivering 0.2 mL in a 1 mL syringe)*



Note: Target is  $\pm 10\%$  of a 0.2 mL dose delivered in a 1 mL syringe. Each box represents the 95% confidence interval of the data set.

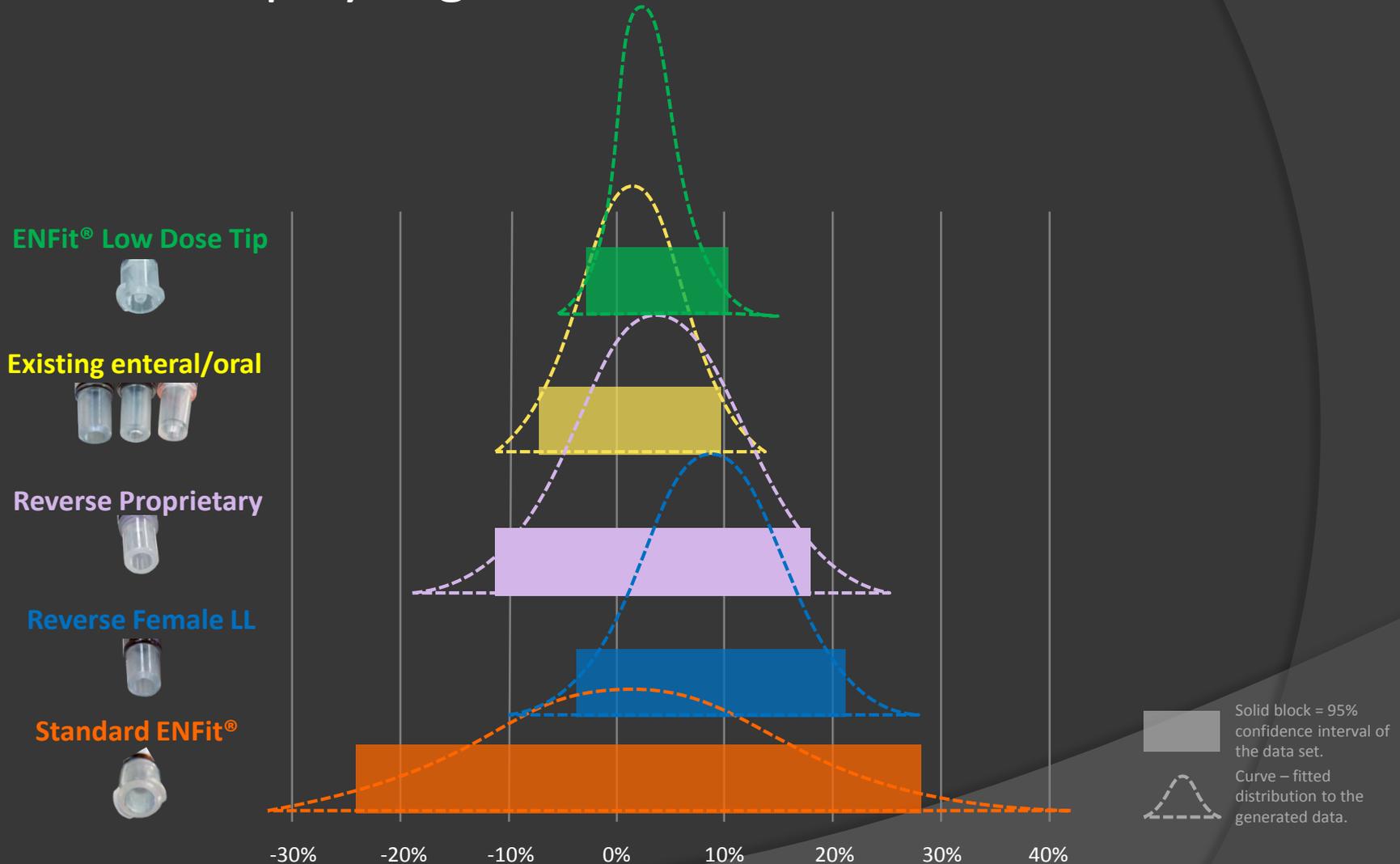
# ENFit<sup>®</sup> Dose Accuracy Solution

- The ENFit<sup>®</sup> Low Dose Tip (*LDT*) syringe was designed to specifically address the dose accuracy concerns
  - Design is proposed for inclusion into ISO 20695 standard and is under review by the committee
- LDT adds an internal male lumen to the standard ENFit<sup>®</sup> female syringe
  - This mimics the functionality of traditional male oral/enteral syringe designs



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# Misconnection Risk Assessment

- The ENFit<sup>®</sup> Low Dose Tip provides a solution for accurate enteral dosing while maintaining a high level of mitigation to the risk of inadvertent tubing misconnections
- The addition of the internal male feature to the standard female ENFit<sup>®</sup> connector was evaluated for tubing misconnections across the other small bore connector designs of the ISO 80369 series
- The conclusion of this analysis was that the ENFit<sup>®</sup> LDT provides a solution for accurate enteral dosing while maintaining a high level of mitigation to the risk of inadvertent tubing misconnections

# Usability Testing Top Level Summary

- ① 148 respondents worldwide representing pharmacy, nursing and caregivers evaluated the ENFit® LDT using current practices and methods for filling and administering enteral doses
- ① The respondents were able to complete the filling or administering of water or thick liquids (Pepto Bismol®/Children's Tylenol®/Paracare®) with the LDT successfully
- ① Responses about the LDT performance were consistent across all user groups, regardless of the tasks evaluated

*"Lumen felt like it connected well with bottle."*

*"Well designed."*

*"I like the secure fit of the syringe on the bottle and the tip cap on the syringe after."*

*"Like how the syringe locks into patient side."*

*"No problems. Easy to use."*

*"Easy to attach and administer."*

Overall, users found the ENFit® LDT design feature acceptable for filling and administering enteral doses

# Recommended Syringe Use

- ◎ Method of filling the syringe (*cup fill vs straw/adapter fill*)
  - Using a straw or adapter to fill the syringe will deliver higher accuracy for each dose, similar to how other reverse orientation syringes are filled currently
  - The straw or adapter reduces the potential for excess residual fluid to be outside the fluid pathway
- ◎ Removal of Residual Fluid
  - The LDT internal feature behaves similarly to the male tip of existing oral/enteral syringes
  - LDT syringes, like standard syringes, should be tapped/flicked/wiped in order to move fluid that may be outside the fluid pathway



# Low Dose ENFit<sup>®</sup> Syringe Conclusion

## **Performance Test Results** *(when used as instructed):*

- Substantially equivalent to standard orientation (male) enteral/oral syringes
- Performs better than Reverse Orientation (female tip) syringes
- Use of an adaptor (such as a straw) provides better performance than a cup fill

## **Misconnection Risk Assessment:**

ENFit<sup>®</sup>, including the Low Dose Tip, mitigates the risk of inadvertent tubing misconnections and provides a clinical benefit

## **Usability:**

No significant difference between use of ENFit<sup>®</sup> LDT syringe and current practice when filling or administering different viscosity fluids or between respondents (Pharmacist, Nurses, or Caregivers)