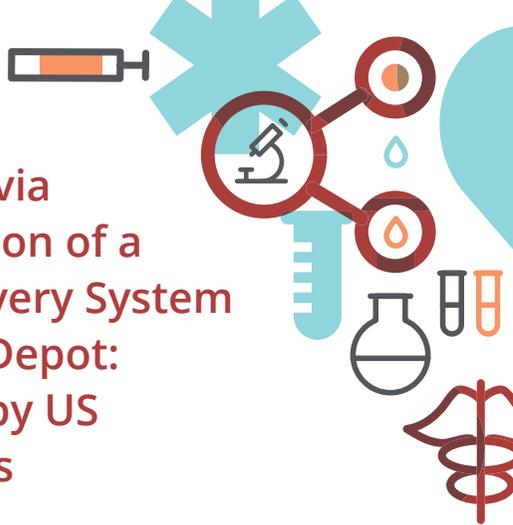


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Enhancing Patient Care via Co-Creation and Validation of a New and Improved Delivery System for Lanreotide Autogel/Depot: Focus on its Evaluation by US Healthcare Professionals



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BACKGROUND: Lanreotide autogel/depot, a somatostatin analog used to treat acromegaly and gastroenteropancreatic neuroendocrine tumors (GEP-NETs), is currently supplied as a sterile, ready-to-use, single-dose prefilled syringe for deep subcutaneous administration. We performed studies to i) gain insights into patient, caregiver, and healthcare professional (HCP) use of the current delivery system (DS) and prototypes, and ii) evaluate use of an improved new DS (NDS).

METHODS: Four human factor (HF) formative studies were conducted (06/2015-09/2016) in participants representing patients with acromegaly (n=33) or GEP-NETs (n=21), caregivers (n=3), HCPs (n=73), and other relevant HCPs (n=2). These studies identified challenges/areas for improvement with the current DS and evaluated NDS prototypes. Formative study-led improvements to the NDS included: ergonomics, robustness of injection process, intuitiveness of use, needle exposure. Lastly, a HF validation study was performed in the US and Germany (05-06/2017) to demonstrate safe and effective use of the final NDS as intended. Validation study inclusion criteria: patients with acromegaly, or non-diagnosed participants with enlarged hands and fingers/dexterity issues willing to self-inject (acromegaly representatives); a caregiver of/patient with a GEP-NET, or non-diagnosed participants willing to inject self/someone else (GEP-

NET representatives/caregivers). Critical tasks were assessed when participants performed two injections with the NDS into a mannequin. Results of the HF validation study are reported.

RESULTS: The US arm of the HF validation study comprised 35 HCPs who did [n=16] or did not [n=19] receive training prior to testing. During the testing session, misuses were reported for 21 (60%) participants, 6 (38%) in the trained group and 15 (79%) in the untrained group. The total number of misuses was 7 in the trained HCP group and 37 in the untrained group. No task errors were specific to the NDS.

CONCLUSION: The ergonomic, robust and intuitive delivery system developed in conjunction with patients, caregivers, and HCPs may further improve patient care.