# Clinical Trials Data KIT - Document 59

# Development of a Manualized Wireless Moisture Pager Intervention for Teaching Toileting in Children With Autism

## Clinical Trial: https://clinicaltrials.gov/study/NCT01978210

"eligibilityCriteria": "Inclusion Criteria:\n\n1. Age 3-6 years old\n2. ASD diagnosis confirmed by licensed professional through administration of the ADOS or ADOS-2, depending upon availability of data\n3. Status consistent with DSM-IV (or DSM-V, depending upon availability) diagnostic criteria for primary daytime enuresis (with exception of criterion that child is at least 5 years old), confirmed by the K- SADS\n4. A positive determination of readiness for toilet training, as determined through aToileting Readiness Checklist developed through a review of relevant literature on toilet training with children with autism (with 4 or more of 7 signs in the checklist, with 3 of these criteria required).\n5. Consent from parent\n\nExclusion Criteria:\n\n1. Medical conditions that would interfere with toilet training procedures (e.g., physical disabilities)\n2. Physical disorder that may contribute to incontinence (e.g., diabetes, urinary tract infection, or seizures)\n3. Anticipation of medication changes to occur during the 3-month intervention period\n4. Medication for enuresis\n5. A parent report that the child has urinated into a toilet 2 times or more when toilet trips are initiated by child, AND/OR 20% or more of the total instances in which a caretaker had initiated a toileting opportunity (to be estimated by study team member during initial conversation. If parent is unsure, they may be asked to monitor toileting behavior for a week, and the team member can call back to review with parent).\n6. Parent report that the child has participated in systematic training efforts, under the guidance of a clinician (e.g., physician, psychologist) for more than 8 weeks (total) in the previous 6months.\n7. Active drug or alcohol use or dependence on the part of the parent that, in the opinion of the site investigator, would interfere with adherence to study re- quirements.",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
 "minimumAge": "3 Years",  
"stdAges": [  
"CHILD"  
]

Question:  
Based on the following clinical trial information, would a patient with a KIT gene mutation be eligible for the clinical trial?

Answer:  
The clinical trial eligibility criteria you provided do not mention anything about genetic mutations, including a KIT gene mutation. The criteria primarily focus on age, ASD diagnosis, primary daytime enuresis, toilet training readiness, and certain medical conditions or treatments related to enuresis or toilet training.  
  
Based on this information, a patient with a KIT gene mutation would not be automatically excluded from participating in this trial, as long as they meet the inclusion criteria and none of the exclusion criteria apply. However, it's always best for the patient or their guardian to discuss specific eligibility with the trial coordinators, who can provide guidance based on all relevant medical details.