- The manuscript by Flodmark *et al* recently published in the journal *Biologics in Therapy* describes a single center experience in Sweden of a switch from an originator biologic to a biosimilar human growth hormone (rhGH).
- Flodmark *et al* concluded that patients were successfully switched with no negative impact on growth and no serious or unexpected adverse drug reactions.
- Unfortunately, the authors fail to mention several limitations to their study which call into question their conclusions.
  - It is unclear from either the current or the previously published manuscript whether the applied model has been suitably validated using an appropriate study population, with adequate sample sizes and suitable treatment duration.
  - Given the heterogeneity in the diagnoses and pubertal status of the population treated with growth hormone, it is not clear whether the same prediction model would be appropriate for the different patient or diagnostic groups included in the current analysis
  - It is also unclear how repeated measures for each individual patient were addressed, given that these affect the reporting of R^2 and standard deviation (SD) and can lead to spurious results.
  - Hey-Hadavi et al reported 8 device-related ADRs in 7 out of 137 subjects (5.1%; injection-site hematoma in 3 and injection-site pain in 5). Compared to this number we find the rate of 18 cases in 98 patients (18.4%) rather high.

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