Drug approval for paediatric IBD and EoE – time to revolutionise: Transitioning from paediatrics to adult care

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A new transatlantic position paper endorsed by EMA and FDA supports extrapolation of adult IBD drug data to adolescents without additional trials and recommends streamlined pharmacokinetic studies for younger children to accelerate pediatric approvals that currently take 6 to 12 years.

KEY POINTS

- The speaker reported that for adolescents over 12 years, effectiveness, safety, and dosing can be extrapolated from adult data, allowing immediate use of any adult-approved drug without further trials.
- For children aged 2 to 12 years, one open-label pharmacokinetic study is needed with short screening, no suboptimal doses, early escape options, and a maximum of two ileocolonoscopies per year.
- The speaker stated that current pediatric approval timelines range from 6 years minimum to 12 years maximum, with entyvio having waited 12 years and hopefully receiving FDA and EMA approval this year.
- In eosinophilic esophagitis transition studies, approximately 60% of patients never established adult follow-up, with gaps of 10 months between visits and nearly 2 years between endoscopies.
- The speaker reported that patients with two or more years without follow-up had 26% increased odds of stricture per year, with 20% returning with food impaction and 30% developing new fibrostenotic features.
- Treatment adherence dropped from 3% non-adherence to 29% after transfer to adult care, and diet adherence fell from 82% when parents managed it to 38% when patients managed it themselves.

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