

QUESTION	ANSWER
1.1 I am a physician and have a patient interested in enrolling into this study. Can you please provide me with the next steps?	<p>Thank you for your interest in possible study participation for SkybriGHt and SkyPASS.</p> <p>To inquire further about becoming a study site or to find a study site nearest to your location, please reach out to skybright_contact@ascendispharma.com or skypass_contact@ascendispharma.com.^{1,2}</p>
1.2 What are the differences between SkybriGHt and SkyPASS?	<p>SkybriGHt is a U.S., multicenter, prospective, non-interventional study that aims to generate evidence on long-term effectiveness and safety of SKYTROFA® (lonapegsomatropin-tcgd) in patients with growth hormone deficiency under routine clinical care.</p> <p>SkyPASS is a prospective, non-interventional (NIS), post- authorization safety study (PASS) that enrolls patients from centers in the U.S. and Europe that aims to further characterize the potential long-term safety risks of lonapegsomatropin-tcgd in lonapegsomatropin-treated patients under real world conditions in the post-marketing setting.</p>
1.3 What is the eligibility criteria needed in order to participate in SkybriGHt?	<p>Inclusion</p> <ul style="list-style-type: none"> • Patients who are on treatment with SKYTROFA® (lonapegsomatropin-tcgd) • Patients being clinically managed in USA • Patients with an appropriate written informed consent/assent as applicable for the age of the patient <p>Exclusion</p> <ul style="list-style-type: none"> • Patients participating in any interventional clinical study



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<p>1.4 What is the eligibility criteria of SkyPASS?</p>	<p>In SkyPASS, patients from centers in Europe and the USA will be eligible for enrolment into the study. Patients may be enrolled in the study if they are on treatment with lonapegsomatropin-tcgd. The decision to treat the patient with lonapegsomatropin-tcgd will be made prior to and independently of the decision to invite the patient to enroll into the study. Both patients naïve to growth hormone (GH) treatment and patients previously treated with GH therapy will be eligible for enrolment.</p> <p>Physicians participating in the study will be instructed to invite all patients who meet study eligibility criteria to enroll until the enrolment period is closed.</p> <p><u>Inclusion Criteria (excluding Germany)</u></p> <ul style="list-style-type: none"> • Pediatric patients with growth hormone deficiency (GHD) who are on treatment with lonapegsomatropin-tcgd • Patients being clinically managed in Europe or the USA • Appropriate written informed consent/assent as applicable for the age of the patient • Patients willing to comply with follow-up requirements of the study <p><u>Exclusion Criteria (excluding Germany)</u></p> <ul style="list-style-type: none"> • Patients participating in any interventional clinical trial for short stature • Patients being treated with a GH or IGF-1 therapy, other than lonapegsomatropin-tcgd, at enrollment • Patients for whom treatment with lonapegsomatropin-tcgd is contraindicated • Patients with closed epiphyses • Patients with active malignant tumors • Patients under anti-tumor therapy within the past 12 months prior to instituting GH therapy • Hypersensitivity to somatropin or any of the excipients in lonapegsomatropin-tcgd
<p>1.5 What is the primary endpoint of the SkybriGHT and SkyPASS studies?</p>	<p>SkybriGHT</p> <ul style="list-style-type: none"> • To describe demographics, clinical characteristics, and GH treatment patterns of patients treated with SKYTROFA in a real-world setting. • To assess clinical outcomes (safety and effectiveness) of patients treated with SKYTROFA <p>SkyPASS</p> <ul style="list-style-type: none"> • To evaluate the occurrence of neoplasms (benign, malignant and unspecified) and type 2 diabetes in patients treated with SKYTROFA under real-world conditions in the post-marketing setting

1. A US Non-interventional, Effectiveness and Safety Study of Patients Treated With SKYTROFA (SkybriGHT). ClinicalTrials.gov Identifier: NCT05820672. Updated May 2, 2025. Accessed June 25, 2025. <https://clinicaltrials.gov/ct2/show/NCT05820672>. 2. A Post-Authorisation Safety Study (PASS) of Patients Treated With Lonapegsomatropin (SkyPASS). ClinicalTrials.gov identifier: NCT05775523. Updated May 4, 2025. Accessed June 25, 2025. <https://clinicaltrials.gov/ct2/show/NCT05775523>.

