Global Patient Registry to Monitor Long-term Safety and Effectiveness of Increlex® in Children and Adolescents With Severe Primary Insulin-like Growth Factor-1 Deficiency (SPIGFD).

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 2 years to 18 years old
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

- For US : patients starting or planning to start or currently receiving treatment with Increlex® therapy for severe primary IGF-1 deficiency as defined by the US Increlex® prescribing information or for growth hormone (GH) gene deletion who have developed neutralizing antibodies to GH.For EU : patients starting or planning to start or currently receiving treatment with Increlex® therapy according to the locally approved product information.
- Parents or legally authorized representatives if applicable must give signed informed consent before any registry-related activities are conducted. Assent from the subject should also be obtained as appropriate

Exclusion Criteria:

- Subject currently participating in an Increlex® clinical trial
- Subject currently participating in any clinical trial for growth retardation
- Patient with any contraindication to Increlex® or any condition subject to special warning as per the locally approved label
- For US patients, these include patients with hypersensitivity to the active substance or any of the excipients, patients with active or suspected neoplasia and patients with closed epiphyses.
- For EU patients: these include patients with hypersensitivity to the active substance or any of the excipients, patients with active or suspected neoplasia or any condition or medical history which increases the risk of benign or malignant neoplasia and patients with closed epiphyses

Conditions & Interventions

Interventions:
DRUG: Increlex®
Conditions:
IGF1 Deficiency

More Information

Description:
The Increlex® Global Registry is a descriptive, multicenter, observational, prospective, open-ended, non interventional, post-authorisation surveillance registry. The main purpose of this global registry is to collect, analyse and report safety data during and up to at least 5 years after the end of treatment in children and adolescents receiving Increlex® therapy for SPIGFD according to the locally approved product information.

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