

PROGRES 2.0

Pfizer Registry of Outcomes in Growth hormone REsearch

PROGRES 2.0 is a Pfizer-sponsored, multi-country, non-interventional, observational, prospective cohort study to obtain real-world data of patients treated with somatrogen (Ngenla®) or somatropin (Genotropin®) under routine clinical care. PROGRES 2.0 is a substudy of and will obtain data from **GloBE-Reg**^{1,2}



An international registry collecting real-world data on novel therapies for endocrine or bone health conditions



Project team based at the Office for Rare Conditions at the University of Glasgow, Scotland, UK



Stakeholders include patients, professionals, scientific organizations, and industry

Background



Daily rhGH or **somatropin** has been used for many years to treat children with GHD and other conditions associated with growth failure³

Somatrogen, a long-acting GH, is approved in certain countries as a once weekly SC injection for the treatment of children and adolescents (3 years and older) with GHD⁴

PROGRES 2.0 will obtain and evaluate data from GloBE-Reg pertaining to somatrogen (Ngenla®) or somatropin (Genotropin®)⁵ use in routine clinical practice²

Objectives



To assess long-term **effectiveness and safety of** and **adherence** to **somatrogen** and **somatropin** (Genotropin®) at the discretion of the treating physician in routine clinical care²

- **Primary:** Describe and compare the effectiveness of somatrogen and somatropin (Genotropin®)
- **Secondary:** Incidence rates of safety events of interest, treatment adherence, and compliance

Study population



Inclusion criteria: Active GloBE-Reg participants prescribed treatment with somatrogen or somatropin (Genotropin®) at the discretion of the treating physician²

Exclusion Criteria: Participation in any interventional clinical trials during the study period²



PROGRES 2.0 – How to participate^{1,2}

PROGRES
PFIZER REGISTRY OF OUTCOMES IN GROWTH HORMONE RESEARCH

PROGRES 2.0 – Globe-Reg Study ID: 202410_MW

#1 Register for Globe-Reg

Click [here](#) or scan the QR code



Access the Registry

You can create your user account now.

To find out more [Click here for the Step-by-Step guides for new user registration](#)

#2 Approvals

Obtain necessary regulatory and institutional approvals for your site. Information on regulatory approvals can be found at <https://globe-reg.net/documents-for-institutional-approval/>

#3 Patient consent

Share participation information sheet and obtain signed informed consent form from patient. Information sheets and consent forms can be found at <https://globe-reg.net/information-sheets/>

#4 Data entry

PI enters data in GloBE-Reg

#5 Eligible cases

GloBE-Reg team identifies eligible cases in the registry and invites centres to join the PROGRES 2.0 substudy

#6 Data transfer

GloBE-Reg transfers data for Pfizer related-products (somatrogen and somatropin [Genotropin®]) to Pfizer at regular intervals

#7 Analysis & dissemination

Pfizer conducts data analysis according to PROGRES 2.0 SAP and disseminates results



Funding opportunities

Available from GloBE-Reg, with potential additional funding from Pfizer. For more information, please contact your local Pfizer medical representative or visit <https://globe-reg.net/globe-reg-collaborative-centre-grants/>

Additional resources



ORC Registries Drop-in sessions

Drop-in sessions occur twice per month. For details and the link to join, visit:

<https://www.gla.ac.uk/orcregistriesdrop-insessions/>



GloBE-Reg FAQs

All GloBE-Reg-related FAQs can be found at <https://globe-reg.net/faqs/>

Abbreviations: FAQ, frequently asked question; GH, growth hormone; GHD, growth hormone deficiency; GloBE-Reg, Global Registry For Novel Therapies In Bone & Endocrine Conditions; hGH, human growth hormone; HV, height velocity; ORC, the office for rare conditions; PI, Principal investigator; rhGH, recombinant human growth hormone; SAP, statistical analysis plan; SC, subcutaneous.

References: 1. GloBE-Reg: Global Registry for Novel Therapies in Rare Bone & Endocrine Conditions. Available at: <https://globe-reg.net/> (accessed Aug 2025). 2. GloBE-Reg: PROGRES 2.0 Study. Available at: <https://globe-reg.net/progress-2-0-study/> (accessed Aug 2025). 3. Somatropin – referral. Available at: [Somatropin - referral | European Medicines Agency \(EMA\)](#) (accessed Aug 2025). 4. Ngenla : EPAR - Product Information. Available at: [Ngenla, INN-somatrogen](#) (accessed Aug 2025). 5. Genotropin – referral. Available at: [Genotropin - referral | European Medicines Agency \(EMA\)](#) (accessed Aug 2025).