Study ID 202501_JG

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Date of Approval: February 2025
Name of study: Safety of long-acting growth hormone in cancer survivors (SAFE-survivors)
Study Period: Mar 2025 – Mar 2035
Summary Growth hormone (GH) treatment is approved for survivors of cancer who have GH deficiency. In addition to the conventional daily formulation, long-acting GH (LAGH) has also been recently approved for the treatment of GHD. This study aims to assess the safety of LAGH compared to the daily GH formulation in cancer survivors, with a specific focus on the occurrence of new cancers and relapses.
Inclusion criteria – All those who receive LAGH following any cancer or tumour diagnosis – All those who receive daily GH following any cancer or tumour diagnosis.
Exclusion criteria – No.
Data to be collected for all participating cases: Core Data Core Data History rhGH Minimum Dataset In addition to the Minimum Dataset, additional cancer-related information and IGF-1 concentration and assay will need to be completed in the Diagnosis and Clinician-Reported Outcome Case Report Forms. Retrospective and longitudinal data are required at 12, 24, 60, and 120 months after initiation of GH treatment.
Data cut timelines: 6 Monthly data tranches with deadlines in March and September
Expected outputs Outcomes will be disseminated as a scientific report and publications.
Publication Plan for authorship in outputs The investigator will adhere to the GloBE-Reg recommendations. All current and future participating centres will be co-authors on all planned publications as long as

they meet the ICMJE criteria listed. The coauthors will include those involved in study design, data provision, data extraction, data analysis and interpretation and those involved in the creation of the outputs. The support of all funders of the GloBE-Reg platform at the time the study was active will be acknowledged.