OP-3-2

USING OBJECTIVE MEASURES AND PATIENT-REPORTED OUTCOMES TO ASSESS DISEASE ACTIVITY FOR PATIENTS WITH ACROMEGALY: BASELINE DATA FROM THE ACRODAT® STUDY

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OBJECTIVES
We report an interim analysis of data captured from 258 subjects from the post-marketing surveillance study to evaluate the clinical utility of ACRODAT®.

METHODOLOGY
This is an international and randomized study (clinicaltrials.gov nct 04349839). Patients were randomly assigned to the ACRODAT® group or the standard practice group and followed-up over a 2-year period. Primary endpoint was the change from baseline in local IGF-I values after 24 months of management. Patients were recruited from medical centres in Denmark (142), France (56), Belgium (34), Spain (21) and Sweden (5). Participating countries also included Italy, Germany, Austria and Switzerland.

RESULTS
One hundred twenty-eight patients were enrolled in the ACRODAT® group and 130 patients in the standard practice group. Patients had a mean (SD) age of 56 ± 13 years, a median time since diagnosis of acromegaly of 114 [5-576] months, and 44 % of the patients were male. Eighty three percent had previously undergone pituitary surgery. Likewise, 83 % were receiving one or more medications for acromegaly at baseline. Investigators used the change in IGF-1 from baseline to determine the disease to be controlled in 182 (71 %) and not controlled in 76 (29 %). Average follow-up period was 11 [0-21] months.

CONCLUSION
This study provided valuable insights on the benefit of ACRODAT® on the normalization or maintenance of normalized IGF-I levels and improvement of disease activity status after a 2 year follow-up period.