ForPatients
*by Roche*

Hemophilia A

# An Observational Study to Evaluate Physical Activity, Bleeding Incidence and Health Related Quality of Life, in Participants With Haemophilia A Without Inhibitors Receiving Standard of Care Treatment

| Trial Status | Trial Runs In | Trial Identifier |
|---|---|---|
| Completed | 1 Country | NCT04165135 ML40983 |

*The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.*

## *Official Title:*

A Multicenter, Non-Interventional Study to Evaluate Physical Activity, Bleeding Incidence and Health Related Quality of Life, in Patients With Haemophilia A Without Inhibitors Receiving Standard of Care Treatment

## *Trial Summary:*

This multicenter, non-interventional, prospective study will collect information about activity status, bleeds, health-related quality of life (HRQoL), health status, and safety in participants with moderate or severe haemophilia A without factor VIII (FVIII) inhibitors, who are being treated in accordance with normal clinical practice.

| Hoffmann-La Roche | N/A |
|---|---|
| Sponsor | Phase |

**NCT04165135 ML40983**
Trial Identifiers

## *Eligibility Criteria:*

| Gender | Age | Healthy Volunteers |
|---|---|---|
| All | #12 Years & # 50 Years | No |

## *Inclusion Criteria:*

- Must own a device compatible with the electronic Patient-Reported Outcome (ePRO) application and with the fitness tracker that will be provided to the patient

- Must have on his/her own device a data traffic availability of at least 2 gigabytes (GB) in total per month intended only for use of study applications and data transfer. If the data traffic plan is exhausted, the participant must be able to connect to a wi-fi network at least once every day in order to transfer the data collected for the study purpose
- Must accept to run on his/her own device the ePRO application and the fitness tracker application
- Must be available to turn on daily the bluetooth connection of his/her own device in order to allow the synchronization with the fitness tracker
- Ability and willingness to comply with all aspects of the protocol, including completion of questions on the ePRO application (for underage population, ePRO questions can be answered by legally authorized representative if deemed necessary)
- Ability and willingness to wear the activity tracking device as indicated
- Diagnosis of severe (FVIII <1%) or moderate (FVIII #1% and #2%) congenital haemophilia A
- No prior history of a positive inhibitor against FVIII. If participant has a previous history of inhibitor development, the participant must have successfully eradicated inhibitors since 3 years.
- At least 150 exposure days of FVIII prior to enrolment

## *Exclusion Criteria:*

- Bleeding disorder other than congenital haemophilia A
- Ongoing (or planned during the study) immune tolerance induction or FVIII prophylaxis if the participant has currently low titre of inhibitors or had inhibitors in the past 3 years
- Previous or concomitant autoimmune or connective tissue disease
- History of or suspected allergy or intolerance to any of the component of the fitness device (e.g., aluminium anodised)
- History of clinically significant hypersensitivity associated with monoclonal antibody
- Obesity (Body Mass Index [BMI] #30 kilograms/metre squared of body surface area [kg/m^2})
- Clinically important cardiovascular, metabolic, endocrine disorders or any other concomitant diseases or conditions that could limit the mobility of participant or could represent any risk according to the Investigator's judgment, or that could interfere with the study evaluation parameters
- Participation in any other interventional clinical trial, including Roche sponsored studies or in any other support program that may include drug administration other than standard clinical practice (e.g., compassionate use, use not in agreement with the authorized indications, patient support programs, etc.)