

# ForPatients

by Roche

Healthy Volunteers

## A Study to Compare Pharmacokinetics (PK) of Etrolizumab Administered Subcutaneously by a Prefilled Syringe With Needle Safety Device (PFS-NSD) or an Auto-injector (AI)

**Trial Status**  
Completed

**Trial Runs In**  
1 Countries

**Trial Identifier**  
NCT02996019 GX29504

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The source of the below information is the publicly available website [ClinicalTrials.gov](https://clinicaltrials.gov). It has been summarised and edited into simpler language.

### *Trial Summary:*

This is a randomized, 2-part, 2-arm, open-label, parallel-group, multi-center study to compare the PK of etrolizumab administered subcutaneously by an AI (test device) or a PFS-NSD (reference device) in healthy participants. The study will comprise a pilot cohort (Part 1) to estimate the geometric mean ratio (GMR) and variability of the maximum observed concentration (C<sub>max</sub>) and area under the concentration-time curve (AUC) to confirm or determine the sample size for the pivotal cohort (Part 2). The pivotal cohort will demonstrate exposure comparability of C<sub>max</sub>, AUC from Hour 0 to the last measurable concentration (AUC<sub>last</sub>), and AUC from Hour 0 to extrapolated infinite time (AUC<sub>0-inf</sub>), values for a single dose of etrolizumab administered subcutaneously either by the AI or the PFS-NSD.

**Genentech, Inc.**  
Sponsor

**Phase 1**  
Phase

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**NCT02996019 GX29504**  
Trial Identifiers

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### *Eligibility Criteria:*

**Gender**  
All

**Age**  
>= 18 Years & <= 55 Years

**Healthy Volunteers**  
Accepts Healthy Volunteers

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