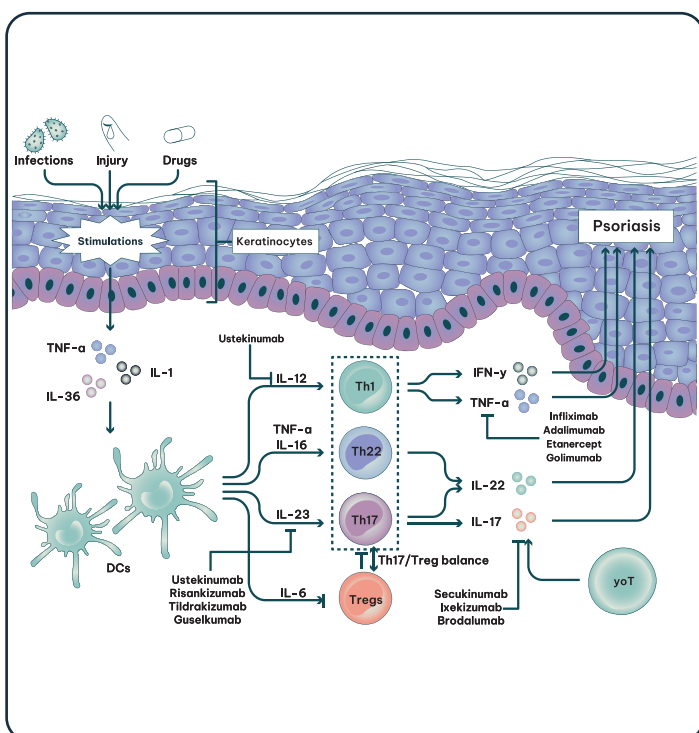


# Unlocking the Pathways of Psoriatic Disease: Advanced Assay Support for Biosimilar Development

Our services support biosimilar developers working in psoriatic and related diseases with advanced, Fab-mediated functional assays. These assays complement primary potency and reporter systems by offering additional insight into biological activity relevant to the therapeutic mechanism.

Strengthen your overall analytical package by orthogonal evidence of functional similarity. By delivering scientifically rigorous data these physiologically relevant assays simplify conversations with regulators and help reduce internal burdens for biosimilar teams.

## Overview of Psoriasis Pathogenesis and Targeted Biosimilar Therapies



## Key mechanism-reflective, Fab-mediated functional assays

### IL-23

- Inhibition of IL-23-mediated IL-17A/F, IL-21, IL-22 secretion in PBMC or T cells
- Inhibition of IL-23-mediated STAT3 phosphorylation in NK or B cell line

### IL-12

- Inhibition of IL-12-mediated secretion of IFN $\gamma$  in primary NK or T cells

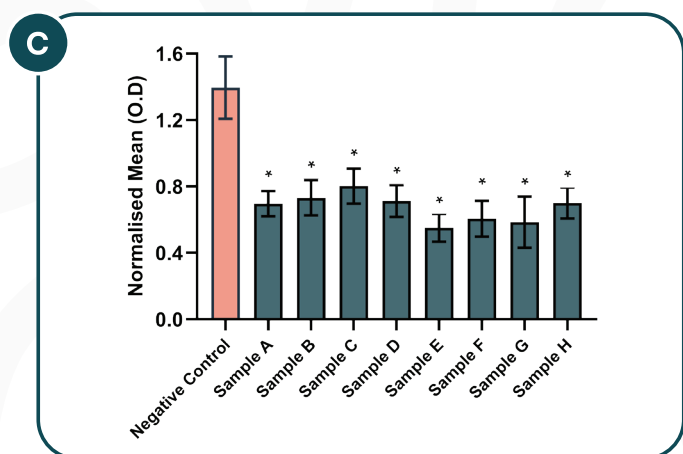
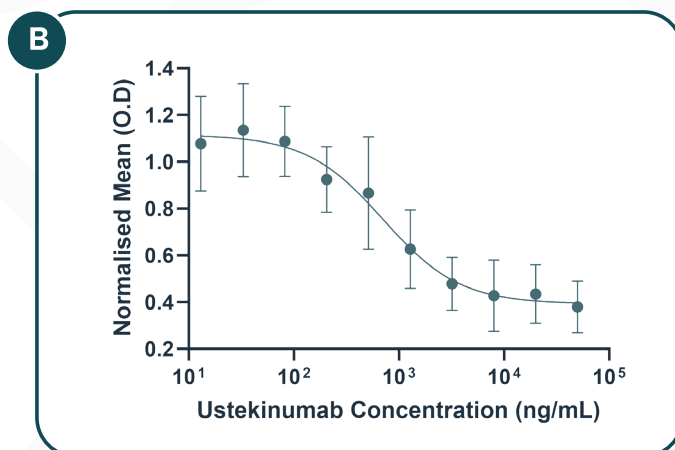
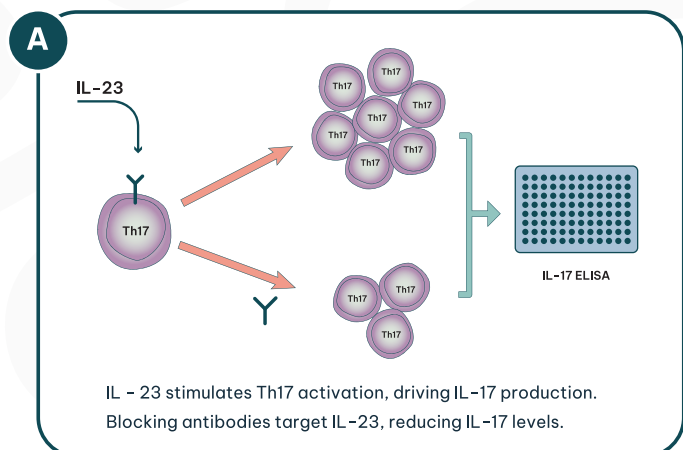
### TNF $\alpha$

- sTNF $\alpha$ -induced apoptosis of monocytic cells
- sTNF $\alpha$ -induced ICAM-1 expression in vascular endothelial cells
- sTNF $\alpha$ -induced IL-8 release in peripheral blood polymorphonuclear leukocytes
- sTNF $\alpha$ -induced IL-8 release in keratinocytes

### IL-17

- Inhibition of IL-17A-induced secretion of IL-6 in primary human fibroblasts and synoviocytes
- Neutralisation of human IL-17A-dependent production of MMP-3 by human synovial fibroblasts

## Example Data: Inhibition of IL-23-mediated IL-17 secretion in PBMC



**Figure A** – The mechanism by which IL-23 stimulates Th17 cell activation, driving the production of IL-17. Neutralizing antibodies target IL-23, thereby reducing IL-17 secretion by Th17 cells. The resulting IL-17 production is quantified using an ELISA assay.

**Figure B** – A neutralization dose-response curve generated for qualitative comparison of antibody function. The curve was fitted using a four-parameter logistic (4PL) model to characterize inhibition of IL-17 secretion following IL-23 blockade. Data points represent the normalised mean, calculated using positive and negative controls.

**Figure C** – Bar graph showing the mean IL-17 response in multiple test samples compared to a negative control. The assay provides a controlled, semi-quantitative evaluation of IL-17 inhibition across different samples. Error bars represent standard deviations from replicate measurements.

## Why choose RoukenBio for Biosimilar development?

- **Mechanism-reflective assays tailored to psoriatic disease** – Our assays are designed to complement top-tier analytical methods, helping to build a robust totality-of-evidence package for regulatory confidence.
- **Access to primary and disease-relevant cells** – We use PBMCs, keratinocytes, endothelial cells and cell lines to ensure physiological relevance and translational value.
- **Trusted by developers and regulators for biosimilars** – We've supported the development of multiple biosimilars that have gone on to receive regulatory approval.



Scan the QR code and download our Biosimilars technical presentation and access sample data.

## RoukenBio - The CRO redefined

Backed by our brilliant minds, we have turned the traditional CRO model on its head, by fostering a collaborative and personalised approach. Our mission is simple:

**Solve problems. Deliver quality data. Propel your drug discovery breakthroughs.**

United by a passion to make sense of complexities and overcome challenges, we apply our specialised knowledge to big-picture thinking. We will explore every option to deliver over and above for your project.

We are thought leaders with a deep understanding of immunology, bioassays, molecular biology and a track record of groundbreaking discoveries and novel cell-based tools.