



A PERFORMANCE  
NOT TO BE MISSED...

## CPD Questionnaire

## Rheumatology

### Title

Infliximab biosimilar  
for autoimmune  
rheumatological  
indications

Based on a presentation by  
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Indicate which one answer is most correct.

**Q1** Which of the following would be required for approval to use an originator biological for patients with ulcerative colitis (UC), but would not necessarily be required to register a biosimilar for the same indication?

- a. Analysis of physicochemical structure.
- b. Phase 1 study to demonstrate pharmacokinetics.
- c. Phase 1 study to demonstrate pharmacodynamics.
- d. Randomised controlled study in patients with UC.

**Q2** Non-medical switching is usually done to

- a. Manage side effects.
- b. Improve efficacy.
- c. Prevent development of anti-drug antibodies (ADAs).
- d. Reduce costs.

**Q3** In the PLANETAS study, the proportion of patients in the CT-P13 group who sustained ASA40 at 54 weeks was

- a. 27.4%
- b. 64.8%
- c. 54.7%
- d. 77.6%

**Q4** In the PLANETRA study, the proportion of patients in the CT-P13 group who sustained ACR70 at 54 weeks was

- a. 21.3%
- b. 36.8%
- c. 45.5%
- d. 66.4%

**Q5** In the PLANETRA study, the proportion of patients with latent TB at 54 weeks was

- a. 7.3%
- b. 9.6%
- c. 11.2%
- d. 12.7%

**Q6** In PLANETRA at week 102, ASAS partial remission rates in the maintenance and switch groups were

- a. 33.3% vs. 34.5%, respectively.
- b. 26.5% vs. 27.5%, respectively.
- c. 20.3% vs. 22.1%, respectively.
- d. 19.3% vs. 23.1%, respectively.

**Q7** The proportion of patients with anti-drug antibodies (ADAs) at week 102 in the PLANETRA CT-P13 maintenance vs. switch extension study was

- a. 34.8% in the switch group.
- b. 44.8% in the switch group.
- c. 34.8% in the maintenance group.
- d. 44.8% in the maintenance group.

**Q8** In the PLANETRA CT-P13 maintenance vs. switch extension study the proportion of ADAs that were neutralising ADAs was

- a. 78%
- b. 86%
- c. 94%
- d. 100%

**Q9** In the NORSWITCH study, the overall population included

- a. 32% of patients with Crohn's disease.
- b. 12% of patients with ulcerative colitis.
- c. 23% of patients with rheumatoid arthritis.
- d. 14% of patients with chronic plaque psoriasis.

**Q10** At week 78 in the NORSWITCH extension study,

- a. 10.6% of patients in the maintenance group had disease worsening.
- b. 44.5% of the switch group remained in remission.
- c. There were no suspected unexpected serious adverse reactions.
- d. Infusion-related reactions occurred in 6% of patients in the switch group.

**Q11** The DANBIO registry documented outcomes in patients who were switched from

- a. INX to CT-P13 due to cost issues.
- b. CT-P13 to INX due to development of ADAs.
- c. CT-P13 to INX due to physician preference.
- d. INX to CT-P13 or CT-P13 to INX.

**Q12** In the Korean Observational Study, in the biologic-naïve AS group who were started on CT-P13, the proportion of patients who achieved BASDAI70 response

- a. Was 6% at week 6 and 12% at week 24 or 30.
- b. Was 18% at week 6 and 42% at week 24 or 30.
- c. Was 28% at week 6 and 50% at week 24 or 30.
- d. Was 32% at week 6 and 69% at week 24 or 30.

**Q13** In the Korean Observational Study, the proportion of RA patients with infusion reactions was

- a. 2%
- b. 7%
- c. 11%
- d. 13%

**Q14** The increase in subjective symptom complaints among patients who were switched from INX to CT-P13 in the BIOSWITCH study is most likely attributable to

- a. Hawthorn effect.
- b. Regression to the mean.
- c. Nocebo effect.
- d. Confounding by indication.

**Q15** The proportion of patients who were satisfied with information about biosimilars provided to them using the Dutch Association of Hospital Pharmacists (NVZA) toolbox Biosimilars was

- a. 66%
- b. 76%
- c. 86%
- d. 96%

Once the questionnaire is completed, please scan it in  
and email to [mail@silentthunder.co.za](mailto:mail@silentthunder.co.za) for marking and certification.

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