Expression of Interest in participating in a non-interventional pharmacovigilance study of Zessly (infliximab)

Expected completion date: 2021 (with the possibility of an extension beyond this date)

The IBD Registry (IBDR) has agreed to facilitate a post-marketing authorisation safety study of the biosimilar product **Zessly (infliximab)** in partnership with **Sandoz Ltd.** The objectives of the study are to identify adverse reactions to the product in a cohort of IBD patients managed in a real-world setting. If your centre is currently prescribing **Zessly** for patients with IBD, we are pleased to invite you to submit an expression of interest in working with IBDR to contribute to the provision of evidence-based data to achieve this outcome.

In the first instance, selection preference may be given to centres that have already obtained (or applied for) Caldicott Guardian approval for participation in the UK IBDR prior to the commencement of the study.

Participating centres will be provided with a simple online WebTool for data capture and all necessary training materials. Study setup and data entry costs will be supported (with initial payment made on successful enrolment of the first five patients into the protocol). Subsequent remuneration will be provided on a per patient basis. This is an observational study only, therefore no additional patient tests or monitoring will be required.

The IBD Registry would be pleased to hear from you if you are interested in participating in this project. Please email **pvsupport@ibdregistry.org.uk** for further information.