

**Adverse events of special interest, related to treatment,
for collection in the PROFILE trial**

Thiopurines (Azathiopurine or 6-Mercaptopurine)

- Pancreatitis (confirmed with either CT scan or amylase/lipase >2x upper limit of normal on local laboratory assay)
- Myelosuppression (WCC <2.0 or neutrophils <1.0)
- Liver toxicity (transaminases >4x upper limit of normal on local laboratory assay)
- Lymphoma
- Skin cancer

Methotrexate

- Pneumonitis
- Myelosuppression (WCC <2.0 or neutrophils <1.0)
- Liver toxicity (transaminases >4x upper limit of normal on local laboratory assay)
- Pregnancy

Anti-TNF (Infliximab or Adalimumab)

- Demyelination
- Active tuberculosis
- Sepsis (requiring hospitalisation)
- Malignancy
- Anaphylaxis