I26. BSRBR: ORIGINS AND AIMS

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Anti-TNF agents were first licensed for treatment of Crohn's disease in USA in 1998 and Europe in 1999. Following successful clinical trials
they were additionally licensed for treatment of RA in 2000. Safety concerns were raised, centred around infections particularly reactivation of latent tuberculosis and possible risk of inducing lymphoma. Thus US based parent companies marketing the initial agents in EU, infliximab (Schering Plough) and etanercept (Wyeth) had a responsibility to undertake post licensing surveillance for safety. They approached a number of investigators in Europe but were advised that, contrary to current practice of such studies being industry lead, the preferred option was for national independent bodies to undertake such work. In 2000 following these discussions EULAR established a working group: The Long Term Toxicity from New Biologic Agents, chaired by Alan Silman (UK) and Lars Klareskog (Sweden). The group recommended that formal national cohort studies should be established which should be at arm’s length from industry. The US companies were persuaded of the value of this independence.

In the UK, BSR was the obvious body to oversee the arrangements for a study and commissioned the then Arthritis Research Campaign at Manchester University to establish the study. This would conform to UK guidelines for Safety Assessment of Marketed Medicines (SAMM) studies and would be the companies’ response to the regulators’ requirements for pharmacovigilance. The key component, which was not a statutory requirement at the time, was the collection of a comparison cohort of non-anti-TNF treated patients, to formally assess any increase in risk. From a scientific perspective there was concern that if there were increased risks of infections or tumours such as lymphoma then this might reflect the severity of the disease rather than any sue of anti-TNF hence the value of a comparison cohort treated with conventional therapy, but for whom it would be possible to adjust for differences in disease severity. At that time it was envisaged there would be relatively slow take up of biologic drugs and that there would be sufficient overlap in severity between the treatment groups to allow for an adjustment. In establishing such a study, the BSR Biologic Register, it was also recognized this was an opportunity to look for clinical benefits. Indeed when NICE issued their initial guidance on the use of anti-TNF the former was conditional on the prescriber registering the patient with the BSRBR. Thus with both the national society and the purse holder supporting the initiative, it was likely there would be strong on-the-ground support from rheumatologists to be involved. This participation is one of the triumphs for specialty in the UK on the international stage.

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