This is a repository copy of *Aligning clinical trials in rheumatoid arthritis with real-life populations*.

White Rose Research Online URL for this paper:
http://eprints.whiterose.ac.uk/91617/

Version: Accepted Version

**Proceedings Paper:**


---

**Reuse**
Unless indicated otherwise, fulltext items are protected by copyright with all rights reserved. The copyright exception in section 29 of the Copyright, Designs and Patents Act 1988 allows the making of a single copy solely for the purpose of non-commercial research or private study within the limits of fair dealing. The publisher or other rights-holder may allow further reproduction and re-use of this version - refer to the White Rose Research Online record for this item. Where records identify the publisher as the copyright holder, users can verify any specific terms of use on the publisher's website.

**Takedown**
If you consider content in White Rose Research Online to be in breach of UK law, please notify us by emailing eprints@whiterose.ac.uk including the URL of the record and the reason for the withdrawal request.
ALIGNING CLINICAL TRIALS IN RHEUMATOID ARTHRITIS WITH REAL-LIFE POPULATIONS
N. C. Navarro Coy$^{1,2,*}$, R. M. West$^{3}$, S. H. Pavitt$^{4}$, K. Hyrich$^{5}$, D. Veale$^{6}$, P. Emery$^{1,2}$, M. H. Buch$^{1,2}$
$^{1}$Leeds Institute of Rheumatic & Musculoskeletal Medicine, University of Leeds, $^{2}$NIHR Leeds Musculoskeletal Biomedical Research Unit, Leeds Teaching Hospitals Trust, $^{3}$Leeds Institute of Health Sciences, $^{4}$School of Dentistry, University of Leeds, Leeds, $^{5}$Institute of Inflammation and Repair, University of Manchester, Manchester, United Kingdom, $^{6}$Dublin Academic Medical Centre, University College Dublin, Dublin, Ireland

My abstract has been or will be presented at a scientific meeting during a 12 months period prior to EULAR 2015: No
Is the first author applying for a travel bursary or an award for undergraduate medical students?: Yes - Travel bursary
Please confirm that you will apply for the travel bursary on the EULAR website www.eular.org: Yes

Background: Despite the huge benefits of biologics in the treatment of rheumatoid arthritis (RA), the level of success reported in Randomised Controlled Trials (RCTs) is not achieved in standard practice (1-5).

Objectives: To establish the level of discrepancy in biologic-naïve cohorts between RCTs and the standard RA population from two local registries (Leeds and Dublin) focusing in particular on patient characteristics.

Methods: A comprehensive literature review was undertaken to identify all published RCTs in biologic-naïve RA patients. The characteristics of patients recruited to the selected RCTs were collated and summarised. Datasets from biologic-naïve patients consented to the biologics registries at the University of Leeds (BMC) and the University College Dublin (UCD) were also collated and summarised. This allowed the identification of the most common patient characteristics representative of RCTs and the general population in RA. The characteristics of patients from the RCTs were compared to BMC/UCD cohorts.

Results: A total of 32 RCTs for biologic-naïve RA patients were identified from the literature review. A total of 1107 datasets from biologic-naïve RA patients were identified from the Leeds (n=684) and Dublin (n=423) registries. The comparison of the patient characteristics from these cohorts showed that patients from RCTs are older than in the registries (mean(SD) age: RCTs=52.6(2.67); registries=50.9(15.06); p=0.0001), however more female patients comprise registries (RCTs=66.14%; registries=73.98%). Almost all disease activity components at presentation are higher in RCTs, leading to significantly higher DAS28 score for patients recruited to RCTs (mean(SD) DAS28-CRP=5.59(0.38); DAS28-ESR=6.56(0.37)) than those in the registries (mean(SD) DAS28-CRP=5.38(1.19); DAS28-ESR=5.76(1.26); p =0.0001)(refer to Table 1). Data on co-morbidities and concomitant drugs is limited in RCTs mainly due to the exclusion criteria that limit the studies population. The data from the registries, albeit incomplete, shows that these patients present with varied co-morbidity, with hypertension (25.9%) being the most common. Other conditions are present in less than 10% of the total.

Image/graph:
Conclusions: This initial evaluation illustrates that the selected RCT populations are not representative of real-life general biologic-naïve RA population, limiting the applicability of RCTs. The higher disease activity inclusion in RCTs illustrates they are yet to adopt the treat to target strategies in the management of RA. Extending the comparison to a larger, registry-based population would add further insights into the disparity between RCT and real-life populations.


Acknowledgements: The ‘BeTheCure’ project as part of the Innovative Medicines Initiative Joint Undertaking, resources of which are composed of financial contribution from the European Union’s Seventh Framework Programme (FP7/2007-2013) and EFPIA companies’ in kind contribution.

Disclosure of Interest: N. Navarro Coy: None declared, R. West: None declared, S. Pavitt: None declared, K. Hyrich: None declared, D. Veale: None declared, P. Emery: Grant/research support from: Abbvie, Bristol-Myers-Squibb, MSD, Roche-Chugai, Pfizer, UCB, Novartis and Lilly. Consultant for: Abbvie, Bristol-Myers-Squibb, MSD, Roche-Chugai, Pfizer, UCB, Novartis and Lilly, M. Buch: Grant/research support from: Abbvie, Bristol-Myers-Squibb, Roche-Chugai, Pfizer and UCB, Consultant for: Abbvie, Bristol-Myers-Squibb, Roche-Chugai, Pfizer and UCB