



UNIVERSITY OF LEEDS

This is a repository copy of *Biologics registers in RA: methodological aspects, current role and future applications*.

White Rose Research Online URL for this paper:
<http://eprints.whiterose.ac.uk/117173/>

Version: Accepted Version

Article:

Nikiphorou, E, Buch, MH orcid.org/0000-0002-8962-5642 and Hyrich, KL (2017) Biologics registers in RA: methodological aspects, current role and future applications. *Nature Reviews Rheumatology*, 13 (8). pp. 503-510. ISSN 1759-4790

<https://doi.org/10.1038/nrrheum.2017.81>

© 2017 Macmillan Publishers Limited, part of Springer Nature. This is an author produced version of a paper published in *Nature Reviews Rheumatology*. Uploaded in accordance with the publisher's self-archiving policy.

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.



eprints@whiterose.ac.uk
<https://eprints.whiterose.ac.uk/>

Fig 1

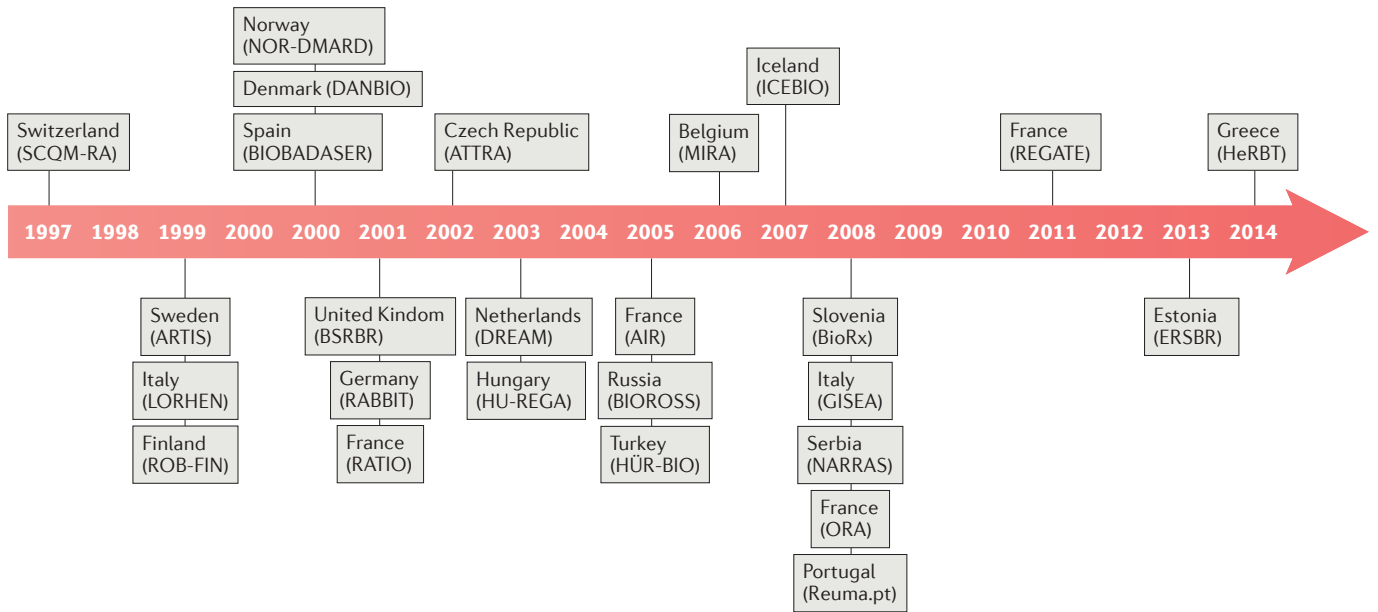


Fig 2

Strengths

- Real-life setting
 - Good reflection of routine clinical practice
 - Good generalizability
 - Unselected population, reflects real-world patients
- Greater power than clinical trials to detect rare events
 - Large number of patients
 - Long observation period
- Can be used to study multiple outcomes and address several research questions
- Can conduct 'add-on' studies to examine further aspects of disease or treatment
- Possibility for linkage to external sources
- Allows predictive analyses, such as
 - Associations between patient and disease characteristics
 - Specific outcomes in both the short-term and long term
- Allows comparative analyses across treatments, such as
 - Switching between treatments
 - Drug survival
 - Drug discontinuation rates

Challenges

- Expensive
 - Often extend over many years
 - May require web-based systems for data capture and input
 - Needs high levels of administrative support
 - Requires meticulous data collection and recording (difficult to sustain)
- Less accurate than clinical trials for monitoring efficacy
 - Subject to confounding by indication, owing to lack of randomization
 - Study validity can be threatened by lack of control group
 - Missing data
- Often 'isolated'
 - May require linkage to external sources
 - May require combination with other datasets to increase power
- Risk of multiple confounders (requiring advanced analytical techniques for accurate data interpretation)
- Associations but no causal-links can be established between exposure variables and outcomes
- Results may be affected by channelling bias