



National biosimilar policies: switching and substitution

Experiences from the Danish DANBIO registry

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DANBIO
Dansk Reumatologisk
Database

Danish health care

Biological treatments are

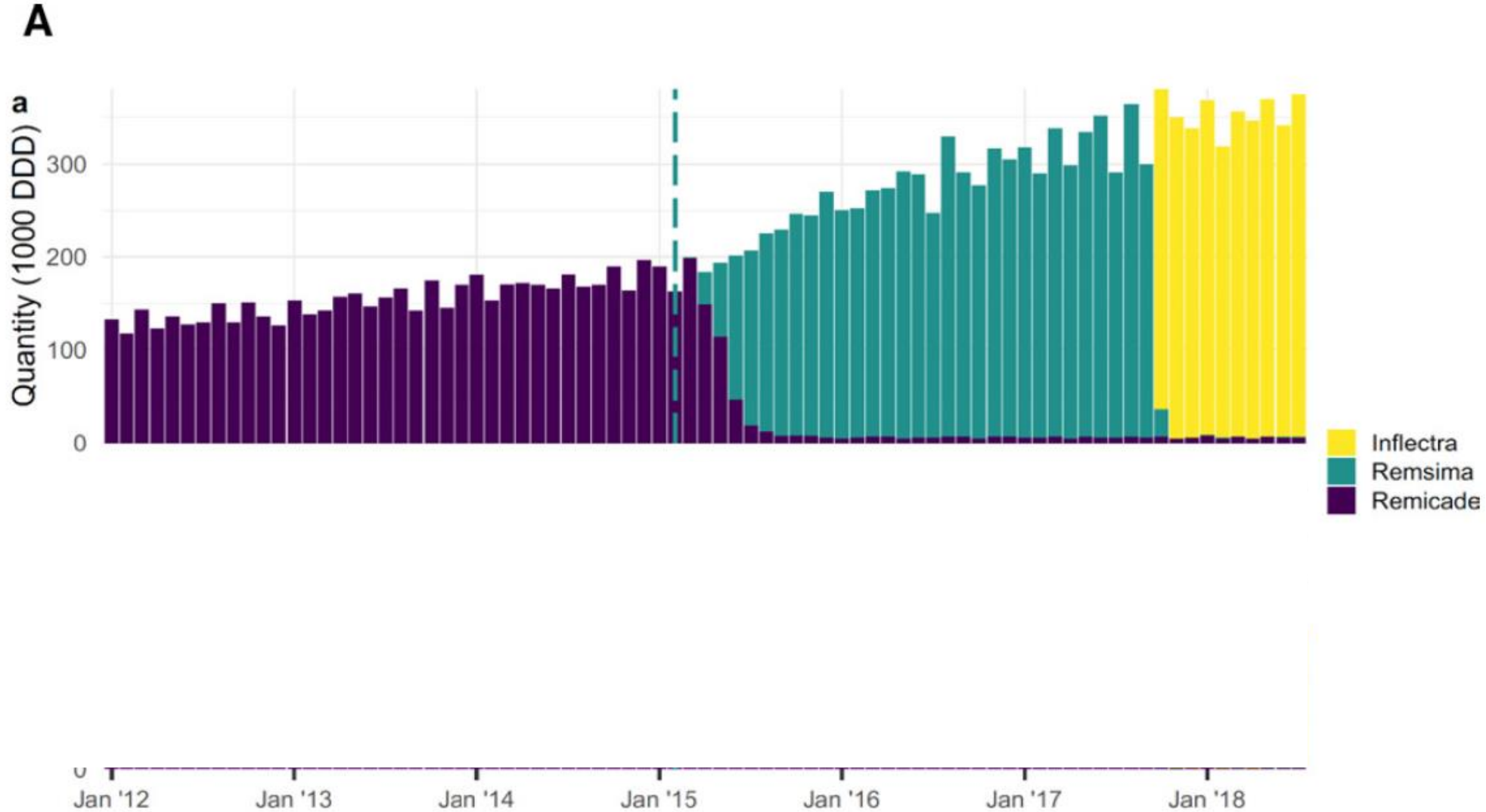
- Tax paid
- Free of charge to the patient – equal access
- Available with liberal access – with all drugs being available
- Provided through hospitals
- Handed to patients every 12 weeks (s.c. treatments)



National tender system - Danish Medicines Council

- Assessment of new medicines including biosimilars
 - Compared to the standard therapy
 - Evaluated by experts in the field (e. g. rheumatologist, clinical pharmacologists, patients)
- National tender process
 - Widest possible competition to reduce costs
 - Suppliers submit their bid and relevant documentation through a secured online system
- National recommendations
 - A prioritized list of medicines to be used for specific indications
 - The cheapest drug gets e. g. 80% of the market share

Biosimilar switches - It all started in year 2015



The dashed vertical line on 13 Feb 2015 represents the date of expiration of the Remicade patent

Denmark: nationwide mandatory switches

Originator bDMARD

→ biosimilar bDMARD

Infliximab (Remicade)

→ CT-P13 (Remsima/Inflectra)

Etanercept (Enbrel)

→ SB4 (Benepali)

Adalimumab (Humira)

→ SB5 (Hyrimoz)

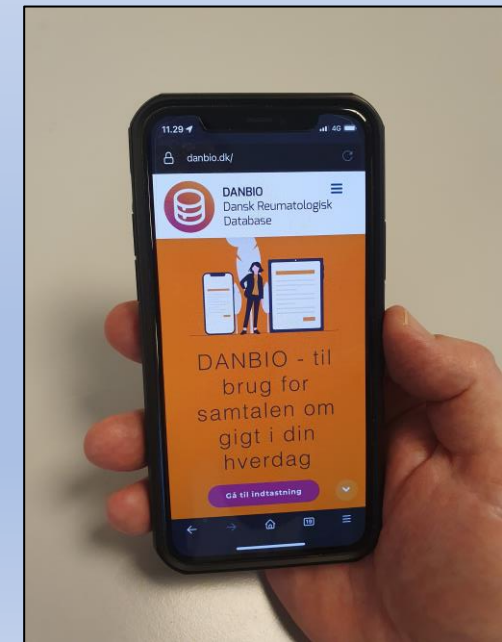
Rituximab (Mabthera)

→ GP2013 (Rixaton)

The nationwide DANBIO registry



- Established year 2000
- Nationwide
- Mandatory to monitor bDMARD treated patients with inflammatory arthritis
- 95% coverage of bDMARDs
- Online data entry by patients and physicians
- >60,000 patients currently monitored



An optimal tool to explore the national strategies

Results from DANBIO

Clinical and epidemiological research

CONCISE REPORT

A nationwide non-medical switch from originator **infliximab** to biosimilar CT-P13 in 802 patients with inflammatory arthritis: 1-year clinical outcomes from the DANBIO registry

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Treatment

CLINICAL SCIENCE

Comparative effectiveness of two **adalimumab** biosimilars in 1318 real-world patients with inflammatory rheumatic disease mandated to switch from originator adalimumab: nationwide observational study emulating a randomised clinical trial

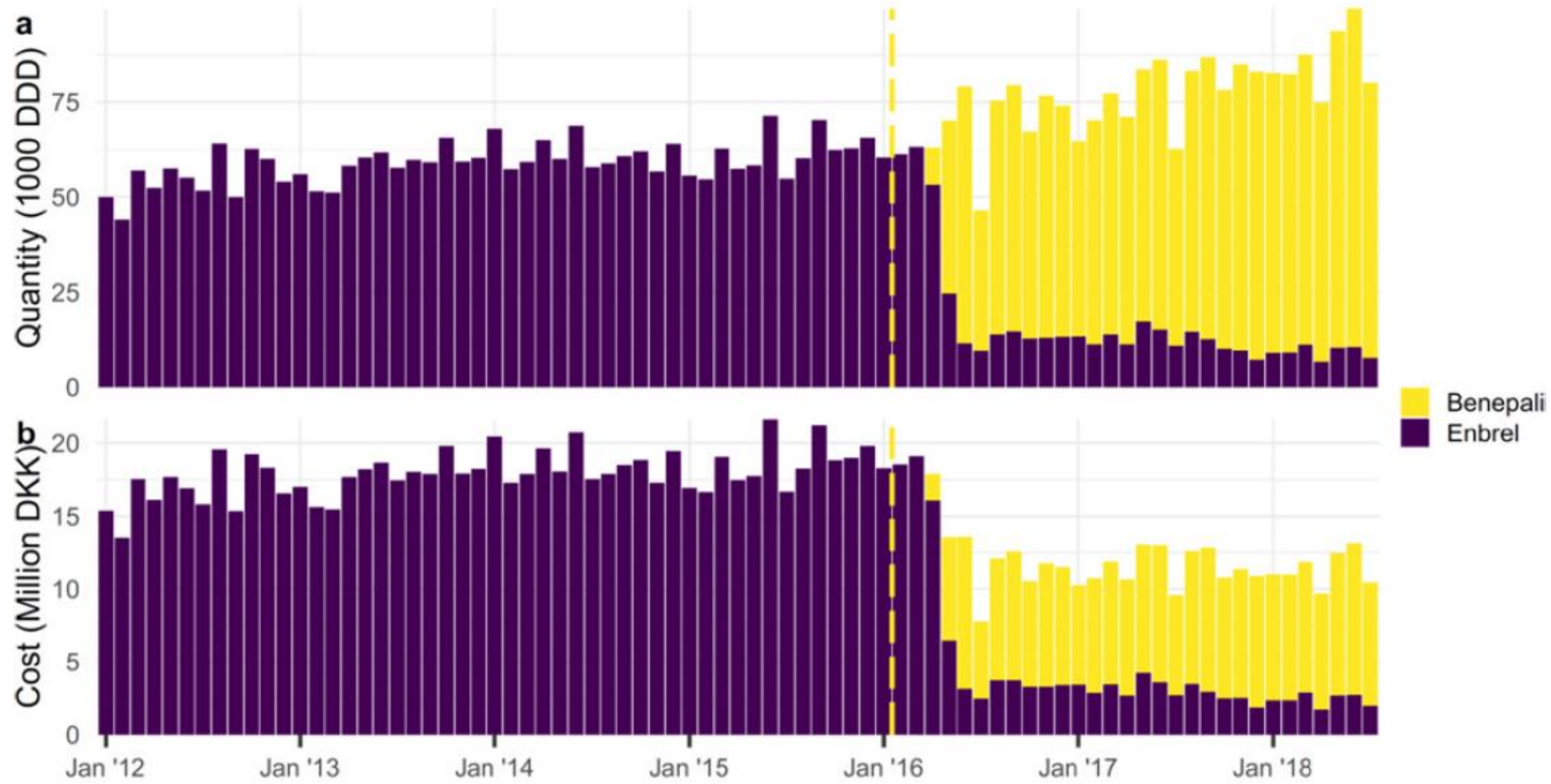
Hafsah Nabi ,^{1,2} Stylianos Georgiadis ,¹ Anne Gitte Loft ,^{3,4} Oliver Hendricks ,^{5,6} Marlene Andersen ,⁷ Stavros Chrysidis ,⁸ Ada Colic ,⁹ Kamilla Danebod ,¹⁰ Mohamad Redha Hussein,¹¹ Maren Høgberget Kalisz ,¹² Salome Kristensen ,¹³ Niels Lomborg ,¹⁴ Natalia Manilo,¹⁵ Heidi Lausten Munk ,¹⁶ Jens Kristian Pedersen ,¹⁷ Johnny Lillelund Raun,¹⁸ Frank Mehnert ,¹⁹ Niels Steen Krogh,²⁰ Merete Lund Hetland ,^{1,2} Bente Glintborg ,^{1,2}

Clinical and epidemiological research

EXTENDED REPORT

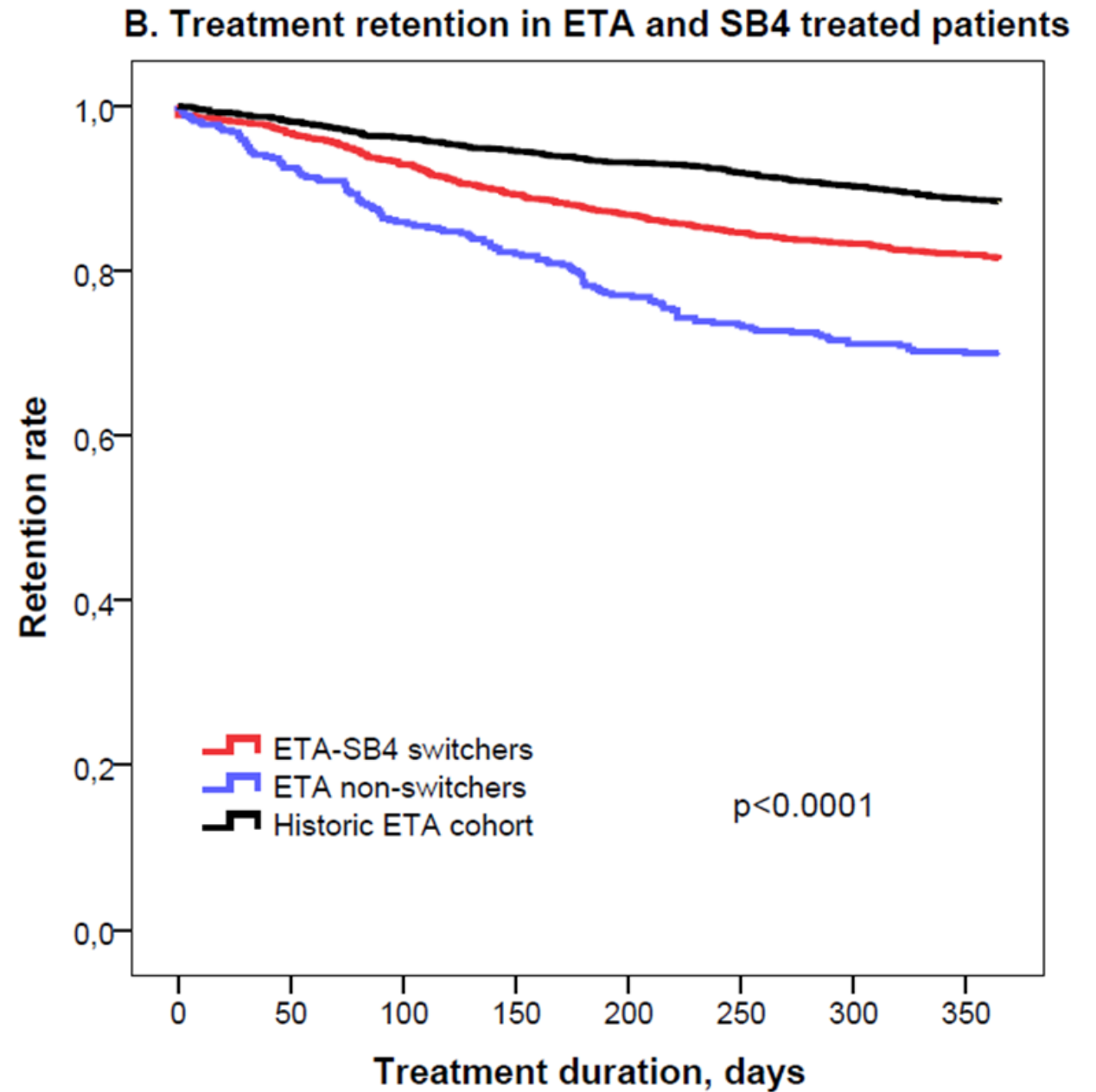
To switch or not to switch: results of a nationwide guideline of mandatory switching from originator to biosimilar **etanercept**. One-year treatment outcomes in 2061 patients with inflammatory arthritis from the DANBIO registry

Bente Glintborg,^{1,2} Anne Gitte Loft,^{3,4} Emina Omerovic,⁵ Oliver Hendricks,⁶ Asta Linauskas,⁷ Jakob Espesen,⁸ Kamilla Danebod,² Dorte Vendelbo Jensen,² Henrik Nordin,⁹ Emil Barner Dalgaard,¹⁰ Stavros Chrysidis,¹¹ Salome Kristensen,¹² Johnny Lillelund Raun,¹³ Hanne Lindegaard,¹⁴ Natalia Manilo,¹⁵ Susanne Højmark Jakobsen,¹⁶ Inger Marie Jensen Hansen,¹⁶ Dorte Dalsgaard Pedersen,¹⁷ Inge Juul Sørensen,^{18,19} Lis Smedegaard Andersen,²⁰ Jolanta Grydehøj,²¹ Frank Mehnert,²² Niels Steen Krogh,²³ Merete Lund Hetland^{18,19}

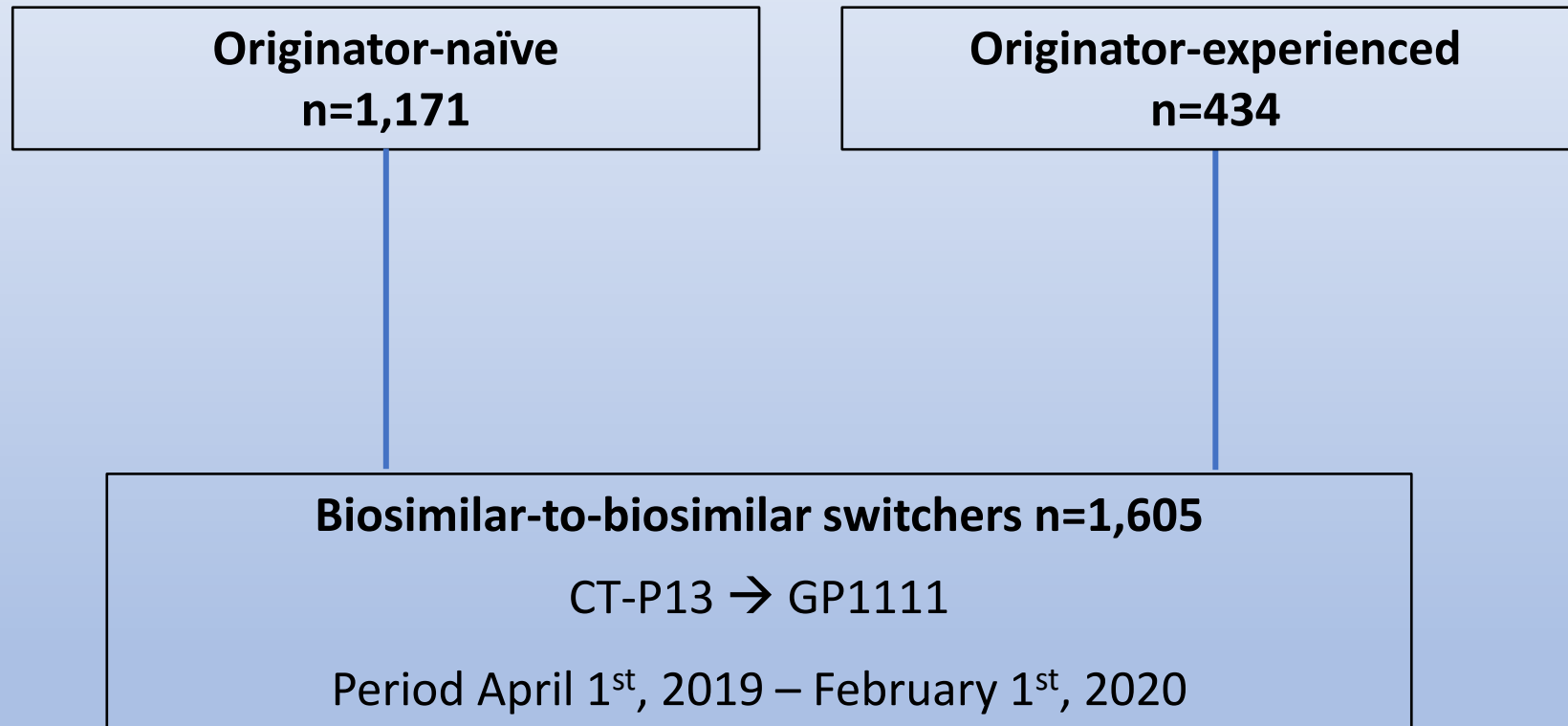
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The dashed vertical line on 1 Feb 2016 represents the date of expiration of the Enbrel patent

Etanercept switch

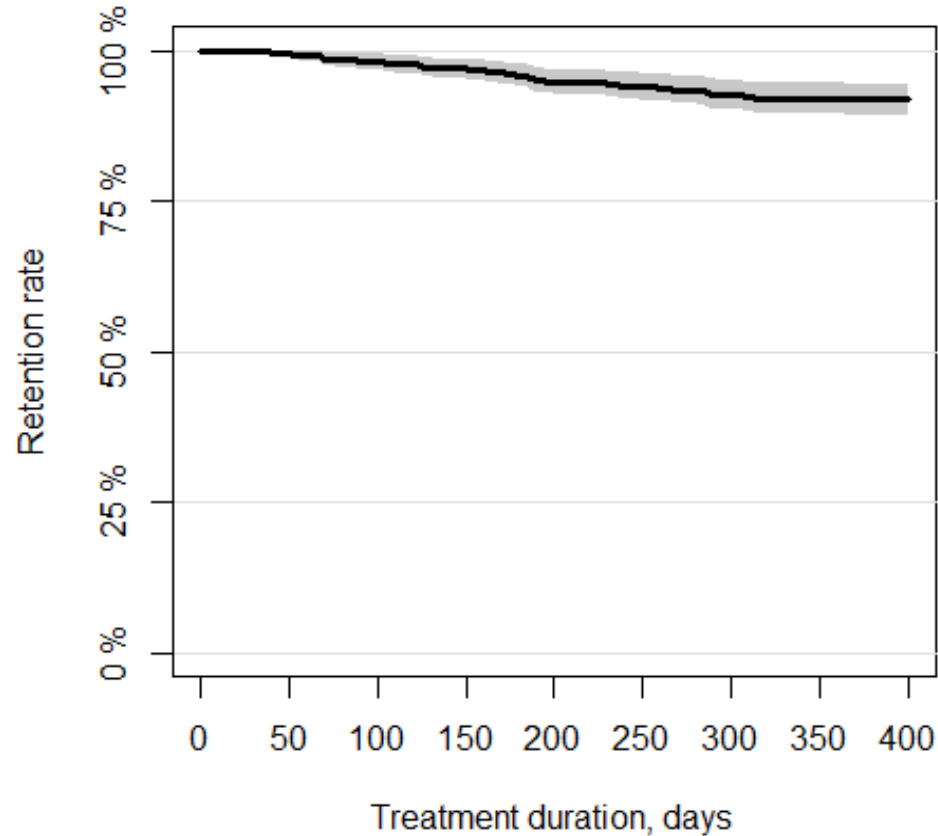


Infliximab biosimilar-biosimilar switching

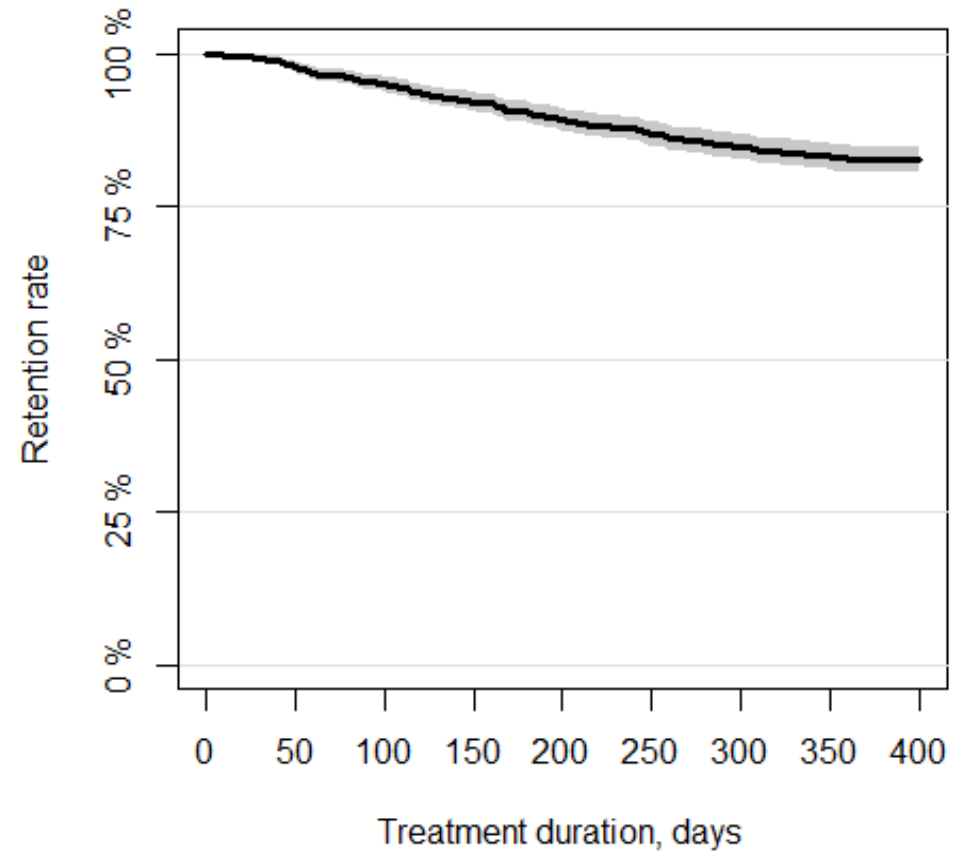


Biosimilar-to-biosimilar infliximab switches

Originator-experienced switchers



Originator-naïve switchers



	Day 0	Day 180	Day 365	Day 0	Day 180	Day 365
No. at risk	434	416	400	1171	1059	969
No. of events	0	18	34	0	112	202
Retention (95% CI)	100.0% (100-100%)	95.9% (94-98%)	91.9% (89-95%)	100.0% (100-100%)	90.4% (89-92%)	82.7% (81-85%)

Conclusion, biosimilars in routine care

In Danish rheumatology

- A range of mandatory biosimilar switches have been performed
- Data from DANBIO have confirmed interchangeability of originators and biosimilars (infliximab, etanercept, adalimumab)

Thank you for your attention

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