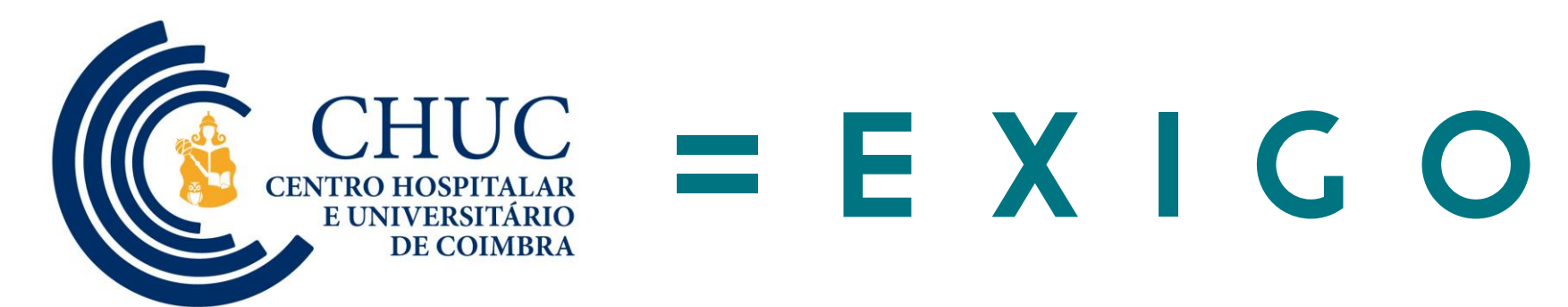


BIOSIMILARS' UTILIZATION UNDER HOSPITAL PHARMACY MANAGEMENT POLICY

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INTRODUCTION / OBJECTIVES

Since October 2017 our university hospital implemented a Fully Integrated Biosimilars utilization management System (FIBS) managed by the hospital pharmacy.

The objective of this study is to assess the effectiveness of hospital pharmacy management in the biosimilars policy at Centro Hospitalar e Universitário de Coimbra (CHUC) Portugal and compare it to other similar public hospitals.

METHODS

FIBS is based on prescription and dispensing by international non-proprietary name. If biosimilars are available, the recommendations from the Hospital Medicines and Therapeutic Committee (HMTc) focus on the biologic drug with the best economic value.

Non-biosimilar utilisation needs clinical justification on a patient-by-patient basis by prescribing physicians. The latter exceptions require validation by the Hospital board, HMTc and hospital pharmacy, which acts as a system gatekeeper.

FIBS allow total traceability including biologic identification by tradename and batch number. Policy implementation was assessed by the extent of switching to, or initiation of, biosimilars by disease area. Policy effectiveness was assessed comparing our hospital biosimilars' utilisation benchmarked to other public hospitals with similar characteristics.

RESULTS

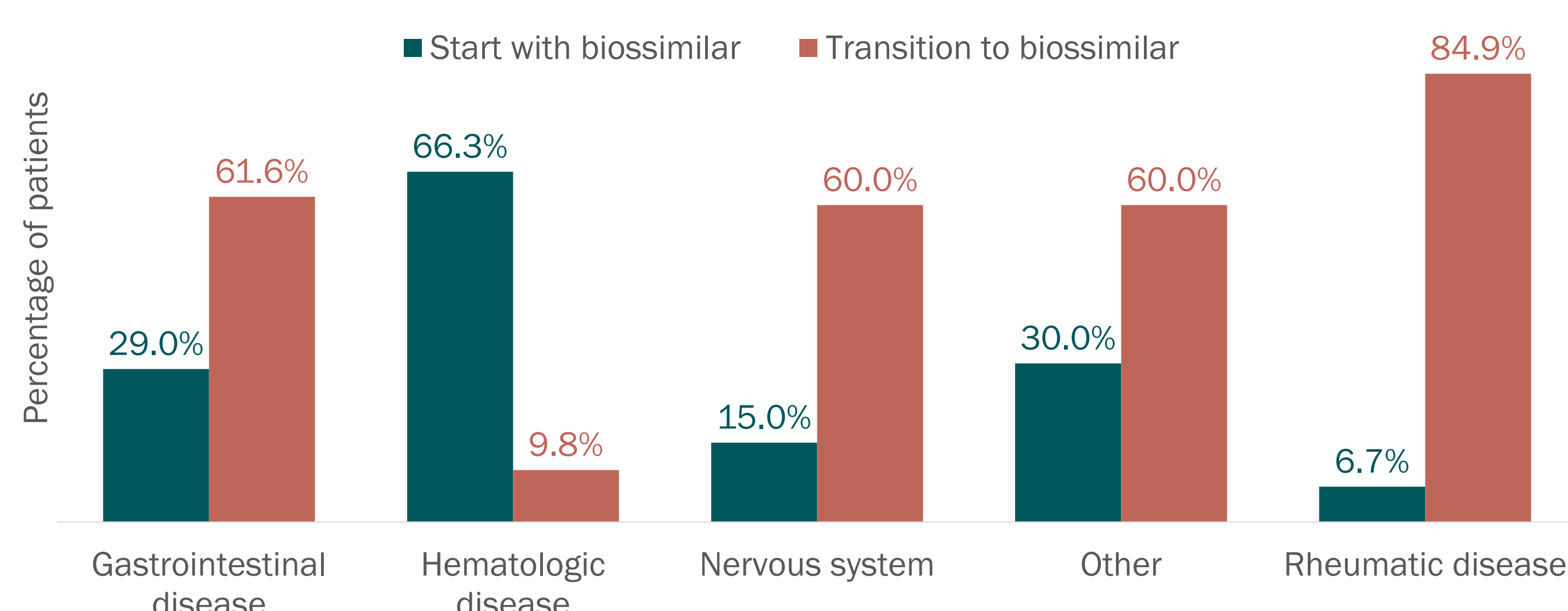
This analysis included all 718 patients using biologic therapy since October 25th, 2017 when biosimilars for etanercept, infliximab and rituximab became available until the date cut-off of September 11th, 2018. Table 1 illustrates the characteristics the patients. The median follow-up time since FIBS implementation was 7.3 months.

Table 1 Patient characteristics

	N=718
Age in years, mean (SD)	52.8 (16.8)
Male, n(%)	330 (46.0)
Diagnostic Disease, n(%)	
Rheumatic disease	225 (31.3)
Hematologic disease	193 (26.9)
Gastrointestinal disease	190 (26.5)
Nervous system	80 (11.1)
Other	30 (4.2)
Biologic therapy	
Etanercept	184 (25.6)
Infliximab	234 (32.6)
Rituximab	300 (41.8)

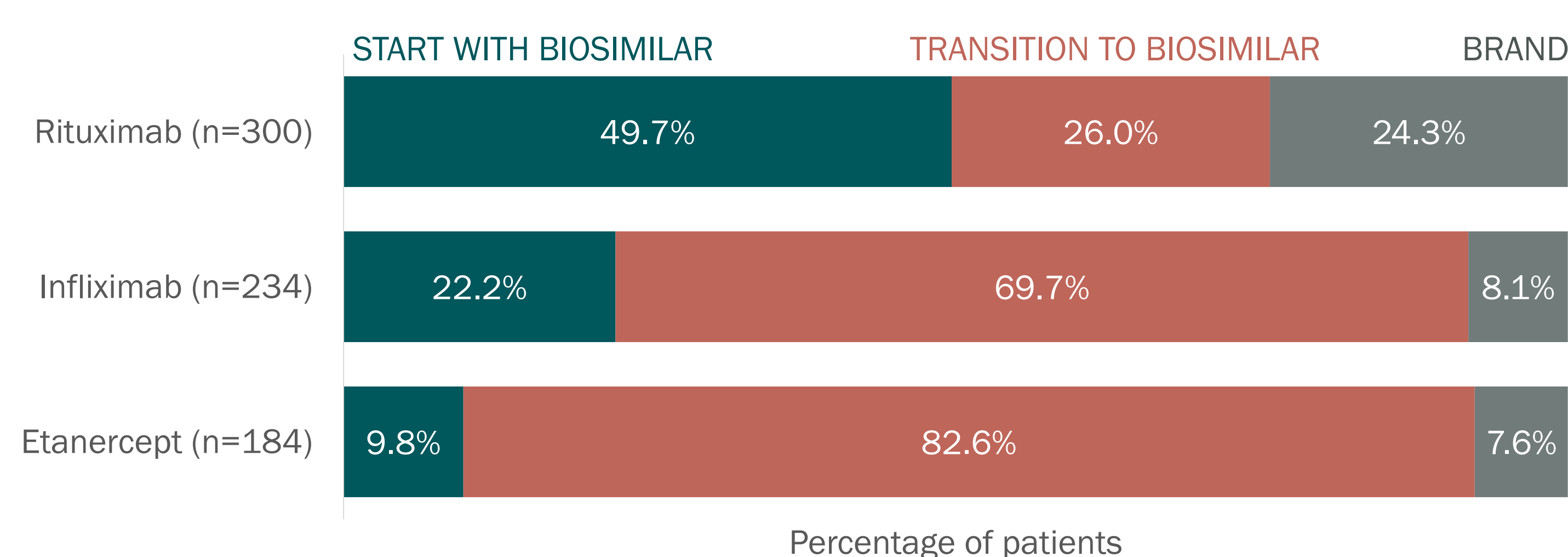
Figure 1 shows the percentage of patients who start their treatment with biosimilar and those who transition to biosimilar by disease diagnosis. A total of 84.9% of rheumatic disease patients had transitioned to biosimilar over the study period while 66.3% of hematologic patients started their treatment with biosimilar.

Figure 1 Percentage of patients in biosimilar according to disease diagnosis



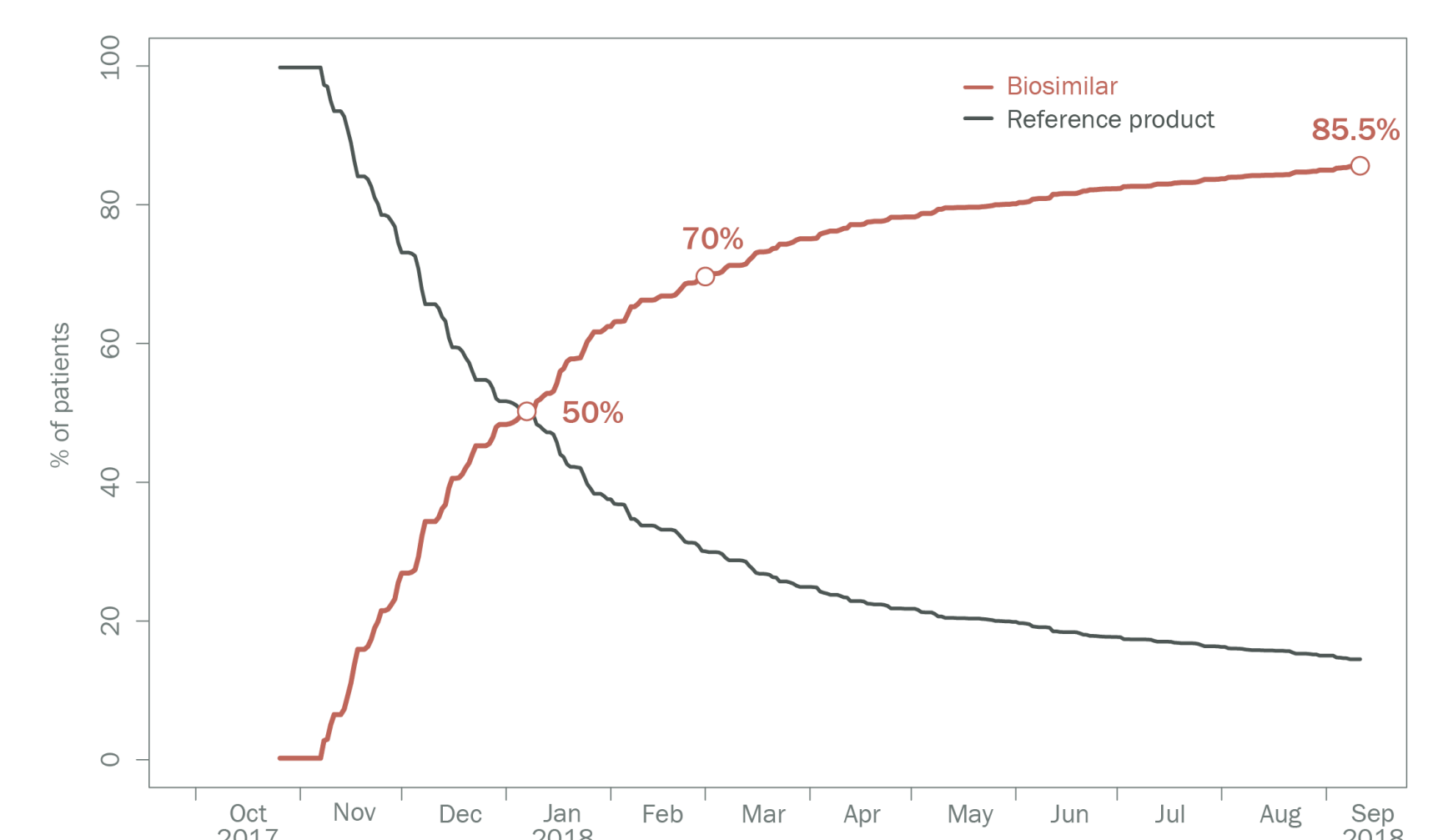
The current overall proportion of patients who start with or transition to biosimilars was 85.2% (N=612 patients) distributed by biologic therapy according to Figure 2. Etanercept was the biologic therapy where the majority of patients transitioned to biosimilar while rituximab had a large proportion of patients starting their biologic therapy with biosimilar.

Figure 2 Percentage of patients in biosimilar and reference product according to biologic therapy



Over the study period, the proportion of patients being treated with biosimilar reached 50% just after 2 months of FIBS implementation (Figure 3). Two months later, this proportion suffered a rapid increase up to 70%. Since then, the proportion of patients continues increasing gradually reaching the value of 85.5% at the end of the follow-up (September/2018).

Figure 3 Effectiveness of FIBS implementation



After one year of FIBS, etanercept and infliximab had almost depleted the biological market at CHUC (92.4% and 91.9% of patients in biosimilar, respectively) while the process for rituximab has been less pronounced (75.7% of the patients in biosimilar).

Figure 4 Effectiveness of FIBS implementation according to biologic therapy

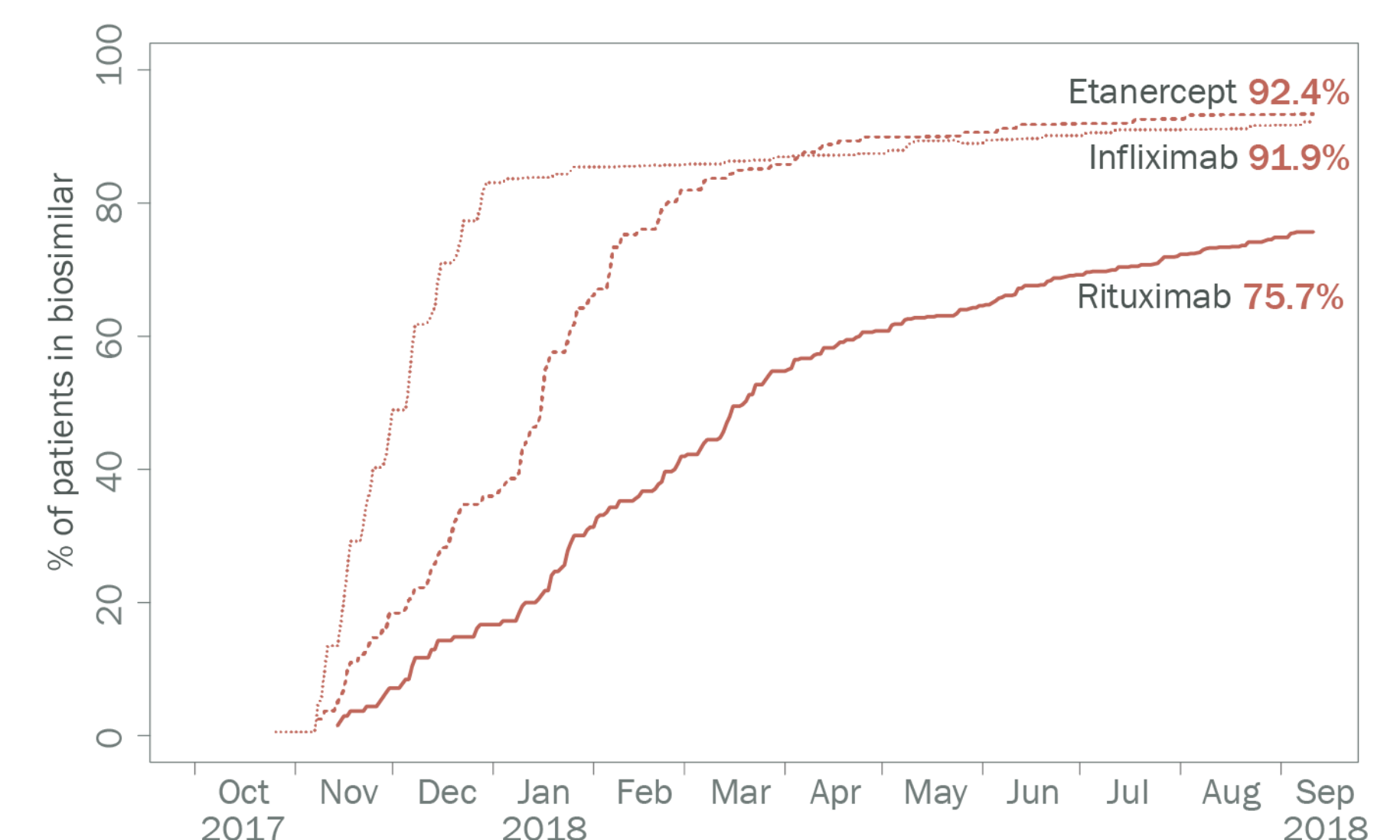
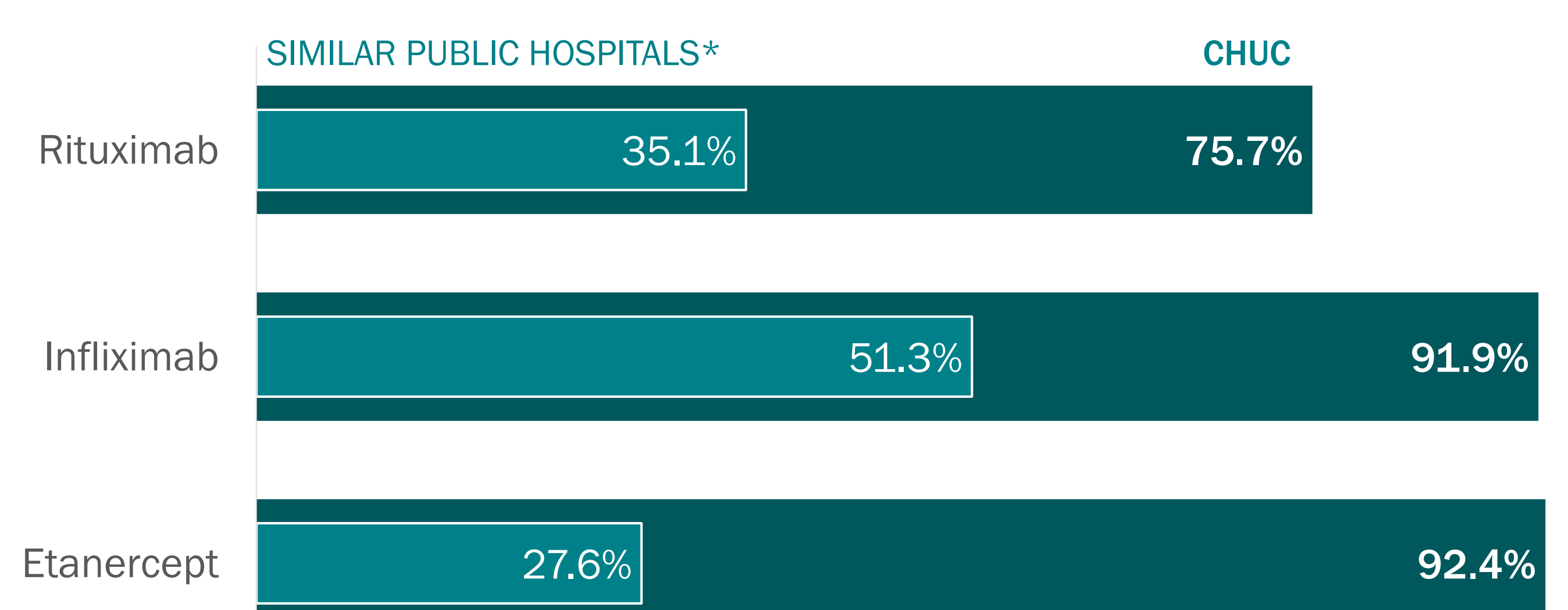


Figure 5 shows that our hospital presented consistently higher rates of biosimilars' utilisation in comparison to other similar public hospitals.

Figure 5 Effectiveness of FIBS implementation compared with similar public hospitals



* Source: <http://www.infarmed.pt/web/infarmed/entidades/farmacia-hospitalar/medicamentos-biossimilares>

CONCLUSION

Hospital pharmacy management of the biosimilars policy was associated with substantial and rapid biosimilars' incorporation and utilisation. Our hospital has one of the best biosimilars' utilisation policy effectiveness in the country.

